Technology and Equipment Committee Meeting

August 29, 2007

MRI Material

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MRI Material

Material Related To

MRI Petition-1: Alliance Imaging

PETITION

TO: Medical Facilities Planning Section
Division of Facility Services
701 Barbour Drive
2714 Mail Service Center
Raleigh, NC 27699-2714

PETITIONER: Shirley Silva
Alliance Imaging Inc.
2428 Belle Terre Drive
Statesville, NC 28625-4331

DATE: July 24, 2007

RE: Petition for Adjusted Need Determination Related to Mobile MRI Scanners

I. Introduction

Earlier in 2007, Alliance Imaging petitioned for a change in Chapter 9 of the Proposed 2008 State Medical Facilities Plan to include the following statement:

"There is no need for any additional mobile magnetic resonance imaging scanners anywhere in the State."

The State Health Coordinating Council denied the earlier petition based on two factors:

- There may still be places where an applicant can demonstrate a need for mobile MRI to improve patient access
- Mobile PET and mobile cardiac catheterization units are more specialized and expensive as compared to mobile MRI. Therefore, it is appropriate for the Plan to state that no need exists for additional mobile PET and mobile cardiac catheterization units but not make a similar statement regarding mobile MRI.

Alliance Imaging respectfully requests that the State Health Coordinating Council reconsider this petition based on updated MRI utilization and mobile MRI inventory data.

II. Rationale for the Proposed Changes

Alliance Imaging offers the following updated information regarding the fixed and mobile MRI inventory and projected future needs for MRI procedures:

A. Growth in MRI Demand Has Leveled Off

The Proposed 2008 Plan shows that 785,445 total MRI procedures were performed in 2005-06 which represents a 65,998 or 9 percent increase over the previous year. The 2007 Plan shows that the previous reporting period 2004-05 had an increase of 65,548 procedures (or approximately 10 percent) over the previous year. These statistics show that growth in MRI demand has leveled off. The following table shows the volumes, inventory and need determinations for the proposed Plan and the previous two years.

	Volumes and Inventory		Need Determinations					
	Annual Volume Previous Yr	Fixed Equiv Total	Standard Fixed MRI	Breast MRI	Extremity MRI	Multi-Position MRI	Other MRI	Total MRIs
2008 Proposed	785,445	251 75	11	0	0	4	0	15
2007 Plan	719,447	237 36	7	0	0	0	0	7
2006 Plan	653,899	222 49	6	1	1	0	0	8

The 2008 Proposed Plan includes 11 need determinations for fixed MRIs based on the standard methodology plus an adjusted need determination for 4 multi-position MRI scanners. The total number of MRI need determinations is substantially larger than the two previous years'. The maximum capacity of these additional 15 scanners is calculated as follows:

15 MRI units x 6,864 MRI procedures = 102,960 procedures annual capacity
(The 6,864 annual procedures is based on the MRI methodology assuming 100 percent utilization.)

The MRI capacity that is being added in 2008 totals 102,960 and far exceeds the actual annual growth of approximately 66,000 MRI procedures that has occurred for each of the two previous years. This means that the proposed additional MRI scanners will probably take volume away from existing mobile units in specific markets.

B. Multi-Position MRI Scanners Can Not Be Installed in Mobile Units

Alliance Imaging has researched multi-position MRI scanners as described by Axiom and confirmed that these machines can not be installed in a mobile unit. Therefore mobile MRI scanners are not a legitimate settlement option to resolve any CON appeals for competitive reviews of multi-position MRI units.

C. The Actual Number of Currently Underutilized Mobile MRI Scanners Should Be Examined

The higher cost and complexity of mobile PET and mobile cardiac catheterization units are certainly legitimate reasons to make the statement in the Plan that no need exists for these units. In total there are far fewer of these types of units as compared to mobile MRI scanners.

The Medical Facilities Planning Section has the data available to determine the number of mobile MRI scanners that were underutilized during the previous year. This information is directly relevant to cost effectiveness and would be helpful to evaluate all mobile technologies.

D. Multiple Approved Mobile MRI Scanners Have Not Been Implemented

CON-approved mobile MRI scanners that are pending implementation include:

Frye Memorial Hospital was approved for a mobile unit on July 15, 2005 (# E-7059-04). No volumes have been reported for this scanner and no progress reports have been received by the CON Section

Alamance Regional Medical Center was CON approved for a mobile unit in November, 2004. Based on the 2007 Mobile MRI Inventory forms this scanner has not been implemented.

Waccamaw Ultrasound & Diagnostic, Inc. d/b/a Waccamaw Imaging (Columbus County) was issued a CON for a mobile MRI scanner effective November 27, 2006; no 2007 mobile MRI inventory form was submitted.

Raleigh Orthopaedic Clinic (Wake County) and Orthopaedic Specialists of the Carolinas (Forsyth County) both obtained CON approval in 2007 to acquire mobile MRI scanners. These units are not yet operational.

The MRI methodology (Table 9O) estimated "fixed equivalent MRI units" that are assigned to the above mobile MRI scanners; these numbers are only estimates of their future capacity based on the number of days per week assigned to the prospective host sites. Since the "fixed equivalent MRI units" data is speculative, as more mobile MRI scanners become CON approved but not operational, the MRI methodology becomes more unreliable.

III. Requested Changes

Alliance Imaging petitions for a change in Chapter 9 of the 2008 State Medical Facilities Plan to include the following statement:

"There is no need for any additional mobile magnetic resonance imaging scanners anywhere in the State."

The requested change is based on the updated utilization and inventory data combined with the abundance of fixed MRI need determinations plus the special need determinations for multi-position MRI scanners.

IV. Adverse Effects if the Changes Are Not Made

The following adverse effects are predicted if the proposed change is not adopted:

- Utilization of the existing mobile MRI scanners statewide will be compromised by the added capacity of recently approved mobile MRI units, plus the abundance of fixed MRI need determinations. Unnecessary duplication of services will result.
- The calculations of "MRI fixed equivalent magnets" will be distorted with even more mobile MRI scanners in the pipeline.
- Mobile MRI sites will be reshuffled, meaning legal challenges will likely occur related to declaratory rulings to add or change those host sites.
- CON applicants in competitive reviews and subsequent appeals may continue to seek mobile MRI units through settlement agreements.

V. Alternatives That Were Considered But Are Not Feasible

Two alternatives that were considered are outlined:

Developing a specific need methodology for mobile MRI scanners is not a feasible alternative because this strategy was previously pursued by Alliance Imaging in the development of the 2003 State Medical Facilities Plan. The previously proposed mobile MRI methodology demonstrated the need for additional mobile MRI scanners and the 2003 SMFP included need determinations for two additional mobile MRI scanners. However, the need methodology that was used to calculate this need was not adopted in the 2003 Plan. Therefore, Alliance Imaging concludes that the Medical Facilities Planning Section is not receptive to a specific need methodology for mobile MRI scanners.

Alliance considered petitioning for an adjusted need determination for only one additional mobile MRI scanner that would be deployed to provide service to new sites in any counties that currently have no mobile MRI host sites or fixed MRI scanners. This scenario could potentially create the opportunity for providers to put forth their best efforts to expand service to rural underserved populations. However, Alliance observed that most of the counties that lack mobile MRI host sites do not have sufficient referring physicians to maintain even one day per week service. Also, the mobile MRI inventory data shows multiple providers with underutilized mobile scanners throughout the state. Therefore no need exists for even one additional mobile MRI scanner at this time.

VI. Evidence That the Proposed Change Will Not Result in Unnecessary Duplication of Health Resources

The proposed change will add no need determinations and will reduce the unnecessary duplication of mobile MRI scanners. Existing mobile and fixed MRI providers with underutilized equipment need a respite from the backlog of previously approved mobile units plus the surge in new MRI need determinations.

VII. Conclusion

There are at least five CON-approved mobile MRI scanners that are now pending implementation. Also there are numerous mobile MRI scanners that performed less than 3,328 unweighted procedures (mobile MRI performance standards 10A NCAC 14C .2703(a) (1) and (2)). Also consider that mobile MRI scanners certainly have the capacity to perform far more than 3,328 annual unweighted procedures.

No need for additional mobile MRI scanners exists as demonstrated by:

- recent MRI utilization data demonstrating that growth in MRI demand has leveled off
- the number of previously approved mobile scanners that are pending
- the abundance of need determinations for fixed MRI and multi-position scanners

Alliance Imaging Inc. requests that the Proposed 2008 Plan include a statement that no need for additional mobile MRI scanners exists anywhere in the State.

Technology and Equipment Committee Meeting

August 29, 2007

MRI Material

Material Related To

MRI Petition-2: Ashe Memorial Hospital

Ashe Memorial Hospital

PETITION FOR AN ADJUSTED NEED DETERMINATION FOR ONE FIXED MRI SCANNER FOR ASHE COUNTY IN THE 2008 SMFP

Petitioner:

Ashe Memorial Hospital
200 Hospital Avenue
Jefferson, North Carolina 28640

R.D. Williams, Chief Executive Officer
(336) 846-7101

To:

Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Requested Change:

Ashe Memorial Hospital (AMH) seeks to provide increased access to fixed MRI services for residents of Ashe County and petitions for an adjusted need determination for one fixed MRI scanner for Ashe County in the 2008 SMFP. There are a number of reasons that justify an adjusted need determination:

- Due to limited mobile access, the hospital is sometimes unable to meet the diagnostic imaging needs of its inpatients and must transfer them to another facility located in another county, further from their home.
- Ashe County has a very high percent of patient emigration seeking available MRI services outside the county.

- The relatively low MRI use rate in Ashe County is indicative of a lack of access to services and of the need for increased access via a full-time fixed MRI scanner at the hospital.
- Given the limited access to mobile MRI services and the inability to increase mobile availability, it is virtually impossible for AMH to experience the growth necessary to trigger a fixed MRI need determination using the standard methodology.
- Ashe County has never had a need determination for a fixed MRI scanner.
- The lack of a need determination for a fixed MRI scanner in Ashe County has negative cost implications for patients and providers.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

Approval of this petition will enable AMH to submit a Certificate of Need application to install the first fixed MRI scanner in Ashe County.

The detailed rationale is described below.

Reasons Supporting Requested Change:

Mobile MRI Access

AMH is a not-for-profit hospital located in the Blue Ridge Mountains, in the northwestern corner of North Carolina. AMH is a rural hospital that has a remarkably sophisticated level of care. Recently, AMH had the honor of being selected the 2006/2007 Outstanding Rural Health Organization of The Year.

AMH began offering MRI services over 14 years ago. As the size of the Medical Staff increased and as patient care protocols trended to regularly utilize diagnostic MRI, AMH responded by contracting with a mobile MRI provider to obtain mobile MRI services. This was the first offering of MRI services in Ashe County and immediately benefited patients. Historically, local residents have demonstrated an increasing demand for MRI services by increasing MRI utilization each year.

Currently, AMH's mobile MRI service is available only two days (Sunday and Wednesday) each week. Due to steadily increasing volumes and the increase in medical practice patterns that utilize MRI as a common diagnostic measure, AMH has requested additional mobile days from its mobile provider. However,

the mobile vendor has been unable to expand its service to AMH due to commitments elsewhere on their routes.

Additionally, as an acute care provider with a busy Emergency Department, AMH needs to have MRI services available 24/7 for inpatients and emergency cases. Due to lack of availability of its mobile scanner, the hospital sometimes is unable to meet the diagnostic imaging needs of some of its inpatients and must transfer them to another facility. Consequently, in 2006, Ashe performed only 75 inpatient MRI procedures compared to 97 inpatient MRI procedures in 2005. In fact, last year, AMH had to transfer ten inpatients to an alternate facility because the mobile MRI scanner was not on-site. Transferring inpatients out of the hospital because of unavailability of a timely MRI scan is a difficult pill to swallow for a small rural hospital, and is costly and inconvenient for the patient and their family.

Based on the Proposed 2008 SMFP data, AMH is 262 weighted MRI scans (484 unweighted MRI scans) away from triggering a need determination for a fixed MRI scanner. However, given the limited access to mobile MRI services and the inability to increase mobile availability, it is extremely difficult for AMH to experience the 40% growth necessary to trigger a fixed MRI need determination. As mentioned previously, due to lack of availability of its mobile scanner, AMH performed only 75 inpatient MRI procedures in 2006 compared to 97 inpatient MRI procedures in 2005.

As stated previously, AMH provides mobile MRI services Sunday and Wednesday each week. While AMH is grateful to have this access, providing mobile MRI services on Sundays is less than ideal. In addition to waiting several days to schedule an exam (there is a 10 day wait for an open MRI appointment as of August 15), patients in the rural South are reluctant to schedule MRI scans on Sundays; therefore, many patients choose to seek alternative, more convenient MRI services outside the county. Consequently, AMH's annualized FY2007 utilization (based on October 2006-June 2007 data) is projected to decrease by nearly 10%.

In summary, despite the best efforts of AMH to improve MRI availability, the current mobile MRI service is insufficient to meet the needs of AMH and of Ashe County residents. The limited MRI access, and inconvenient days of availability are not conducive to enabling AMH to increase its MRI volume, and thereby trigger need for a fixed MRI scanner via the standard SMFP methodology. It is very clear that Ashe County merits an adjusted need determination in recognition of these unique circumstances.

MRI Emigration

Residents of Ashe County are utilizing MRI services, as they and their physicians recognize the benefits of this powerful diagnostic imaging modality. However, each year an increasing number of local patients are forced to travel out of county for MRI services because they are not readily available locally.

AMH, the only hospital in Ashe County, is located in the heart of the Blue Ridge Mountains. The closest fixed MRI provider is located nearly 40 minutes away in Boone. According to patient origin information provided by the Division of Health Service Regulation (DHSR) Planning Section, in 2006, over 73% of Ashe County MRI patients travel to Watauga County for MRI services because they are not available on a full-time basis locally. It is important to consider this statistic from an individual perspective to appreciate the significance. As the following table summarizes, during the past four years nearly 3,000 Ashe County residents have had to travel to Watauga County for MRI services.

Ashe County MRI Emigration

Year	Total Ashe County MRI Patients	Ashe County Patients Traveling to Watauga County	% Emigration to Watauga County
2003	693	496	71.6%
2004	947	633	66.8%
2005	993	651	65.6%
2006	1,508	1,106	73.3%

Source: 2003-2006 MRI Patient Origin Report provided by DHSR Planning Section

Please note that in 2006, 1,106 patients traveled to Watauga County for fixed MRI services. This number nearly doubled from the previous year. This is simply not acceptable. It is unreasonable to expect that residents of Ashe County should have to travel so far outside their own county to obtain timely access to MRI services. Even for a rural mountainous community, MRI is considered a mainstream diagnostic imaging service, and thus should be available locally on a full-time basis. In 2007, there is no good reason why North Carolina residents should travel to a medical center located 40 minutes away in another county. Furthermore, this is not consistent with the State's basic health planning principles of expanding access to services, and of promoting cost-effective approaches.

There are negative implications associated with leaving Ashe County for MRI services. Patients may experience increased costs associated with travel and time spent away from work. Ashe County residents are, on average older than

residents of North Carolina. According to North Carolina demographic estimates, in 2007 approximately 19% of Ashe County residents are 65 and older compared to only 12% in the State[1]. This is important to consider because of the need to provide adequate access to fixed MRI services for medically underserved, i.e. Medicare and Medicaid. Patients may also experience delays obtaining diagnoses. It is inconvenient from a patient perspective to travel out of the county for MRI services that could be expanded locally. Emigration will simply continue if Ashe County fails to implement full-time fixed MRI services amidst its aged population and growing MRI utilization.

Geography

The geography of the region that AMH serves makes it important for the hospital to obtain a full-time fixed MRI scanner. The image below illustrates that the terrain is very mountainous between Ashe and Watauga counties.

Mountainous Ashe County

[1] North Carolina Office of State Budget and Management

Consequently, when the mobile MRI scanner is not on-site at AMH, a patient from Ashe County in need of MRI services must experience long travel times to receive an MRI scan. Winter weather can create dangerous driving conditions, making it even more difficult to travel to a distant county. Many of the roads in and surrounding Ashe County are small, two-lane roads that can become icy or hazardous during inclement weather. In an emergency, it may not always be possible for a patient to be immediately transferred to another facility for MRI services when the mobile scanner is not on-site at AMH. For these reasons, Ashe County residents need an adjusted need determination so that a fixed MRI scanner can be installed at AMH.

The geography of Ashe County can also have a direct impact on AMH's ability to provide mobile MRI services. In 2006, AMH experienced at least three or four days when the mobile MRI scanner could not travel to the hospital because winter weather conditions, e.g. snow and ice. This is significant when considering the fact that the mobile MRI scanner is only scheduled on site for 104 days per year. Further, 2006 was considered a mild winter; there have been previous winters when AMH has lost several more days of mobile MRI access because of treacherous driving conditions.

In the recent past, the SHCC has determined that hospitals located in mountainous regions indeed have special circumstances that may justify an adjusted need determination for a fixed MRI scanner. For example, in 2004, Highlands-Cashiers Hospital submitted a petition for an adjusted need determination based on its inability to obtain mobile MRI services for residents of Macon County. Similarly, AMH, on behalf of Ashe County residents, now seeks an adjusted need determination based on related circumstances.

MRI Use Rate

Increased MRI capabilities have changed the diagnostic approaches to many illnesses and disease states. MRI is the imaging modality of choice for an increasing number of conditions that local physicians see each day. As a result, MRI utilization rates are trending upward nationally, in North Carolina, and despite the limited access, in Ashe County as well. Please see the table below summarizing recent North Carolina utilization rates.

North Carolina MRI Utilization Rate History

Year	State Population	Number of Procedures	Use Rate/1000	Percent Change
2001	8,219,494	485,808	59.10	--
2002	8,336,829	543,635	65.21	10.3%
2003	8,417,255	592,888	70.44	8.0%
2004	8,562,210	653,504	76.32	8.4%
2005	8,663,674	719,447	83.04	8.7%
2006	8,860,341	785,445	88.65	6.8%

Source: Population data from N.C. State Office of Planning
MRI volume data from State Medical Facilities Plans
Totals may not foot due to rounding.

As noted in the table above, in FY2006 the North Carolina MRI use rate was 88.65 (per 1,000 population). Based on population data and MRI patient origin data provided by the DHSR Medical Facilities Planning Section, Ashe County has experienced an MRI use rate significantly lower than that of the State.

In FY2006, Ashe County's MRI use rate was 58.50 (1,508/ (25,778/1,000)), or 34% below the North Carolina MRI use rate. The low use rate in Ashe County is not the result of a lack of need for local fixed MRI services; rather it is indicative of a lack of access to services, and therefore of the need for increased access to fixed MRI scanners for local residents.

Ashe County has a lower MRI use rate compared to the State because the existing, limited mobile MRI service cannot adequately accommodate current demand for MRI services in Ashe County. This is further supported by the increasing number of Ashe County residents traveling out of county or MRI services. Thus, an additional fixed MRI scanner is needed in Ashe County.

SMFP MRI Need Determinations

As stated previously, AMH has provided MRI services for over 14 years. Since the implementation of a MRI need methodology in the 1999 SMFP there have been over 100 individual need determinations for fixed MRI scanners in North Carolina. However, none of these need determined fixed MRI scanner have been awarded in Ashe County.

The MRI need methodology has been modified three times in the six years since its inclusion in the SMFP. Two of these modifications occurred in the 2005 and

2006 SMFP. In the Proposed 2008 SMFP, AMH is 262 weighted MRI scans away from triggering a need determination for a fixed MRI scanner. AMH supports the SMFP MRI need methodology; however, based on the fact that in 2006 an additional 455 Ashe County residents traveled to Watauga County for MRI services, it is virtually impossible for AMH to experience the volume growth (484 unweighted MRI scans) necessary to trigger a fixed MRI need determination.

Adverse Effects on the Population of the Adjustment for a Dedicated Breast MRI Scanner is Not Made

Should this petition not be granted, residents of Ashe County would have to continue with the status quo. AMH would continue providing the existing, limited mobile MRI services. Ashe County patients requiring MRI scans will continue to face lengthy wait times because the mobile MRI scanner is only available on Sunday and Wednesday each week.

The status quo is not a cost effective alternative. Inpatients who need an MRI scan may incur an extended stay to have an MRI scan performed. This, in turn, increases AMH's length of stay and cost of operations. As AMH transitions toward to Critical Access Status, AMH's ability to reduce operating costs will only reduce healthcare costs because the State reimburses Critical Access hospitals based on cost rather than prospective payment. Thus, an adjusted need determination to include one fixed MRI scanner in Ashe County is a cost effective alternative to the status quo.

Mobile MRI scanners provide a valuable service to North Carolina; however, it is not the most cost effective alternative for Ashe County patients. Hospitals and freestanding facilities that host mobile MRI scanners experience higher costs due to the fee that must be paid to the mobile provider for each MRI scan. In FY2006, AMH's total annual cost related to its mobile MRI service was $438,700. Based on AMH's access two days each week, this equates to an average $4,218 each day ($438,700/104 mobile days per year). Unfortunately, these higher costs must be transferred to the patients and payors.

If an adjusted need determination is not granted for Ashe County, patients and providers will experience increased charges and costs, respectively.

No Unnecessary Duplication of Services

Approving this petition will not result in any unnecessary duplication of services in Ashe County. AMH is the only MRI provider in the county. As stated previously, residents of Ashe County do not have timely and convenient access to local fixed MRI services. Patients currently travel at least 40 minutes to Watauga County for fixed MRI services. Should AMH obtain a fixed MRI scanner, it would discontinue its mobile MRI service.

Conclusion

In summary, AMH seeks an adjusted need determination in the 2008 SMFP to include one fixed MRI scanner for Ashe County, based on the following reasons:

- Ashe County has a high percent of patient emigration seeking MRI services outside the county.
- The low use rate in Ashe County is indicative of a lack of access to services and of the need for increased access to a fixed MRI scanner.
- Due to limited mobile access, the hospital is sometimes unable to meet the diagnostic imaging needs of its inpatients and must transfer them to another facility.
- Given the limited access to mobile MRI services and the inability to increase mobile availability, it is virtually impossible for AMH to experience the volume growth necessary to trigger a fixed MRI need determination.
- Ashe County has never had a need determination for a fixed MRI scanner.
- The lack of a need determination for a fixed MRI scanner in Ashe County has negative cost implications for patients and providers.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

MOUNT JEFFERSON FAMILY MEDICINE

200 Hospital Avenue, Suite 3 • Jefferson, NC 28640
Telephone 336-846-7433 • FAX 336-846-7878

EDWARD J. MILLER, M.D.
VICKIE F. INGLEDUE, M.D.
M. CHAN BADGER, M.D.
MELINDA D. WONSICK, M.D.

August 3, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
701 Barbour Drive
2714 Main Service Center
Raleigh, NC 27699-2714

Re: Petition for Adjusted MRI Need Determination for Ashe County by Ashe Memorial Hospital, Inc.

Dear Mr. Elkins:

I am writing in support of Ashe Memorial Hospital's petition for an adjusted MRI need determination in Ashe County. As a physician that frequently utilizes MRI for evaluation and diagnosis of many conditions and diseases, I fully support Ashe Memorial's petition for one MRI scanner in Ashe County to be included in the 2008 State Medical Facilities Plan.

MRI capabilities have changed my diagnostic approach to many illnesses and disease states, as I suspect they have for many of the physicians in the medical community. MRI scanning is often the more superior imaging modality for an increasing number of disease states we see each day. But presently, my patients must wait several days to get an MRI scan in Ashe County. It is essential for patients to have timely access to MRI services.

Ashe County is also experiencing increases in population growth and an increasing demand for medical services, especially MRI. In order for the local medical community to remain responsive to patient care needs, it is vital that Ashe County have adequate resources to accommodate demand.

For these reasons, I fully support Ashe Memorial's petition for an adjusted MRI need determination for Ashe County.

Sincerely,

Vickie F. Ingledue, M.D.

200 Hospital Ave., Suite 7
Jefferson, NC 28640
(336) 846-7238

HIGH COUNTRY FAMILY MEDICINE

Kevin J. Kurtz, M.D.
Leigh Bradley, M.D.
Chris Campbell, M.D.

All Physicians are Board Certified by the American Academy of Family Physicians

August 3, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
701 Barbour Drive
2714 Main Service Center
Raleigh, NC 27699-2714

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For these reasons, I fully support Ashe Memorial's petition for an adjusted MRI need determination for Ashe County.

Sincerely,

Kevin J. Kurtz, M.D.

Chauncey B. Santos, M.D. P.C.
Orthopedic Surgeon

P.O. Box 880
Jefferson, NC 28640

Telephone (336) 846-1222

August 3, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
701 Barbour Drive
2714 Main Service Center
Raleigh, NC 27699-2714

Re: Petition for Adjusted MRI Need Determination for Ashe County by Ashe Memorial Hospital, Inc.

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Ashe County is also experiencing increases in population growth and an increasing demand for medical services, especially MRI. In order for the local medical community to remain responsive to patient care needs, it is vital that Ashe County have adequate resources to accommodate demand.

For these reasons, I fully support Ashe Memorial's petition for an adjusted MRI need determination for Ashe County.

Sincerely,

Chauncey B. Santos, M.D. P.C.

Technology and Equipment Committee Meeting

August 29, 2007

MRI Material

Comments Related To

MRI Petition-2: Ashe Memorial Hospital

Ashe Memorial Hospital

SHCC Public Hearing Presentation Comments for
Adjusted Need Determination for Fixed MRI Scanner in Ashe County
July 13, 2007

Good afternoon, my name is R.D. Williams. I am the Chief Executive Officer at Ashe Memorial Hospital. I am here today to speak on behalf of our petition for an adjusted need determination for one fixed MRI scanner in Ashe County to be included in the 2008 State Medical Facilities Plan. We will submit the petition to the Medical Facilities Planning Section by the August 3rd due date.

Ashe Memorial Hospital is a not-for-profit hospital located in the Blue Ridge Mountains, in the north-western corner of North Carolina. Ashe Memorial is a rural hospital that has a remarkably sophisticated level of care. Recently, we had the honor of being selected the 2006/2007 Outstanding Rural Health Organization of The Year. Our hospital is the only provider of MRI services in the county; however, due to mobile MRI availability, access is very limited for local residents. Thus, we are requesting that a need determination be included in the 2008 SMFP for a fixed MRI scanner in Ashe County. There are a number of reasons that justify an adjusted need determination:

Ashe Memorial began offering MRI services over 14 years ago. As the size of the Medical Staff increased and as patient care protocols trended to regularly utilize diagnostic MRI, Ashe Memorial responded by contracting with Alliance Imaging to obtain mobile MRI services. This was the first offering of MRI services in Ashe County and immediately benefited patients. Local residents have demonstrated an increasing demand for MRI services by increasing MRI utilization at Ashe Memorial each year.

Currently, our mobile MRI scanner is available only two days (Sunday and Wednesday) each week. Due to steadily increasing volumes and the increase in medical practice patterns that utilize MRI as a common diagnostic measure, Ashe Memorial Hospital has requested additional mobile days from its mobile provider. However, Alliance Imaging is unable to provide any additional days to us.

Additionally, as an acute care provider with a busy emergency department, Ashe Memorial needs to have MRI services available 24/7 for inpatients and emergency cases. Due to lack of availability of its mobile scanner, the hospital sometimes is unable to meet the diagnostic imaging needs of some of its inpatients and must transfer them to another facility. In fact, last year, we had to transfer several emergency and inpatients to an alternate facility because the mobile MRI service was not on-site. Consequently, in 2006, Ashe performed only 75 inpatient MRI procedures compared to 97 inpatient MRI procedures in 2005.

Ashe Memorial Hospital, the only hospital provider in Ashe County, is located in the heart of the Blue Ridge Mountains. The closest fixed MRI provider is located nearly 40 minutes away in Boone. According to patient origin information provided by the Division of Facility Services Planning Section, over 65% of Ashe County MRI patients must travel this distance for MRI services because they are not readily available locally. This is simply not acceptable from our perspective.

The geography of the region that Ashe Memorial serves makes it important for us to provide fixed MRI services. The terrain is very mountainous between Ashe and Watauga counties. Consequently, a patient from Ashe County in need of MRI services when the mobile MRI scanner is not located at the hospital must experience long travel times to receive an MRI scan. Also, winter weather can create dangerous driving conditions making it even more difficult to travel to fixed MRI sites. Many of the roads in and surrounding Ashe County are small, state roads that can become very icy during inclement weather. In an emergency, the chance exists that a patient may not be immediately transferred to another facility for MRI services. For these reasons, it can be extremely difficult for residents of Ashe County to travel outside of the county for MRI services.

Based on the Proposed 2008 SMFP data, Ashe Memorial is only 484 MRI scans away from triggering a need determination for a fixed MRI scanner. However, given our limited access to mobile MRI services and the inability to increase mobile availability, it is extremely difficult for Ashe Memorial to experience the 40% annual growth necessary to trigger a fixed MRI need determination. As I mentioned previously, due to lack of availability of its mobile scanner, Ashe performed only 75 inpatient MRI procedures in 2006 compared to 97 inpatient MRI procedures in 2005. It is virtually impossible for us to trigger a need determination due our limited mobile MRI access.

Another reason that supports our petition for an adjusted need determination is the fact that MRI utilization in Ashe County is far below the State's average use rate. Ashe County's MRI use rate is less than half of the North Carolina MRI use rate. The low use rate in Ashe County is not the result of a lack of need for local

fixed MRI services; rather it is indicative of a lack of access to services and of the need for increased access to a fixed MRI scanner for local residents. Ashe County's projected population growth further emphasizes the need for access to a fixed MRI scanner; otherwise the county use rate will continue to represent an underserved population.

The lack of a need determination for a fixed MRI scanner in Ashe County has negative cost implications for patients and providers, and thus adversely effects this population. Small rural hospitals, like Ashe Memorial, that host mobile MRI scanners experience higher costs due to the fee that must be paid to the mobile provider for each MRI scan. Unfortunately, these higher costs are often transmitted to the patients. As a current provider of mobile MRI services, Ashe Memorial calculates that, on average, approximately $300 per scan is paid to the mobile MRI provider. Thus, in FY2006, this equates to approximately $369,000 in fees that were paid to our mobile MRI provider. These costs are passed along to consumers.

Finally, aside from the lack of availability, mobile MRI services are not the most effective option from an operational or patient perspective. For example, reliability is not equivalent to that of fixed scanners. Each year Ashe Memorial experiences several days when its mobile MRI scanner is down due to factors associated with travel of the mobile unit. This results in an unnecessary delay of patient access to MRI services. Additionally, physical access to mobile service is less than ideal, because mobile MRI scanners are physically located outside a facility on a concrete pad. Physical access to mobile MRI scanners can be especially problematic in inclement weather. This creates an unnecessary burden for patients, especially the elderly or patients already in pain.

In summary, Ashe Memorial seeks an adjusted need determination to include one fixed MRI scanner in Ashe County in the 2008 SMFP, based on the following reasons:

- Due to limited mobile access, the hospital is sometimes unable to meet the diagnostic imaging needs of its inpatients and must transfer them to another facility.
- The low use rate in Ashe County is indicative of a lack of access to services and of the need for increased access to a fixed MRI scanner.
- The lack of a need determination for a fixed MRI scanner in Ashe County has negative cost implications for patients and providers
- Mobile MRI services are not the most effective option from an operational or patient perspective.
- Given our limited access to mobile MRI services and the inability to increase mobile availability, it is virtually impossible for Ashe Memorial

to experience the 40% annual growth necessary to trigger a fixed MRI need determination.

We feel there is a clear need for an additional fixed MRI scanner in Ashe County. We hope you will support us in this effort by approving this petition for an adjusted need determination. Thank you.

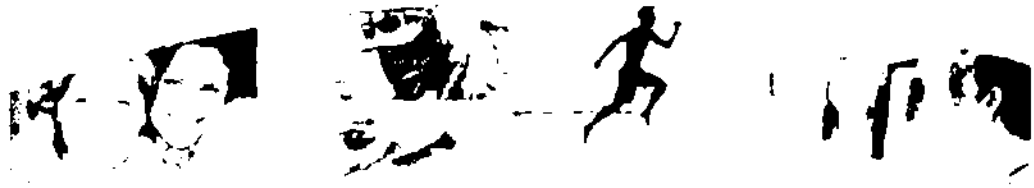
Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Petition – 3: Greensboro Orthopaedics, P.A.



PETITION FOR AN ADJUSTED NEED DETERMINATION FOR ONE FIXED MRI SCANNER FOR GUILFORD COUNTY

Petitioner:

Greensboro Orthopaedics, P.A.
1401 Benjamin Parkway
Greensboro, NC 27408-4518

John S. Nosek, MPA, CMPE
Executive Director
336-545-5000

To:

Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Requested Change:

Greensboro Orthopaedics, P.A. (GOC) seeks an adjusted MRI need determination, specifically to include one fixed MRI scanner in Guilford County in the 2008 State Medical Facilities Plan (SMFP).

There are a number of reasons that justify an adjusted need determination

- The MRI utilization in Guilford County is well above the State's average use rate
- Guilford County has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties.
- Guilford County had the second highest mobile utilization in FY2006 of all North Carolina counties, and its proportion of mobile MRI scans to total MRI scans is increasing.
- Of the 12 counties with fixed MRI need determinations in the Proposed 2008 SMFP, nine have a lower population to fixed MRI ratio than does Guilford County.
- The percentage of Guilford County residents who obtain MRI scans in other counties has been steadily increasing the past three years.
- Because of the high level of mobile MRI utilization in Guilford County, the lack of a need determination for an additional fixed MRI scanner in Guilford County has negative cost implications for patients and providers, thus adversely effects this population.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

Approval of this petition will enable any eligible applicant the opportunity to submit competitive Certificate of Need applications proposing the best plan for addition of a fixed MRI scanner in Guilford County.

The detailed rationale is described below.

Mobile MRI Utilization

Currently, Guilford County has four providers that are exclusively mobile sites, Greensboro Orthopaedics, Guilford Neurosurgical, High Point Orthopaedics and Southeastern Orthopaedic Specialists. In FY2006, these four providers performed 11,988 mobile MRI procedures. In addition, three other mobile MRI host sites performed an additional 5,685 mobile MRI procedures, for a total of 17,673 mobile MRI procedures performed in Guilford County. This is the second highest utilization of mobile MRI services in North Carolina, behind only Mecklenburg County, which has a population nearly twice as large as that of Guilford County. The table below provides mobile MRI utilization for the ten counties with the highest mobile MRI utilization in FY2006.

FY2006 Mobile MRI Utilization
Top 10 Counties

County	Mobile
MECKLENBURG	20,118
GUILFORD	17,673
WAKE	10,645
NEW HANOVER	10,362
FORSYTH	7,356
MOORE	6,664
CATAWBA	6,592
GASTON	4,203
ONSLOW	3,659
RUTHERFORD	3,360

Source: Proposed 2008 SMFP

The FY2006 data is not an anomaly. For the past three years, mobile utilization in Guilford County has steadily increased. In fact, mobile utilization in Guilford County triggered a need for a fixed MRI scanner in the 2001, 2002, 2003 and 2005 SMFP. The following table provides historical mobile MRI utilization for Guilford County.

Guilford County Historical Mobile MRI Utilization
FY2000-FY2006

Year	Mobile Utilization	% Increase
2000	6,217	--
2001	8,905	43.2%
2002	11,058	24.2%
2003	13,194	19.3%
2004	14,680	11.3%
2005	15,307	4.3%
2006	17,673	15.5%

Source: 2002-2007 SMFP, Proposed 2008 SMFP

As shown in the previous table, mobile MRI utilization in Guilford County experienced an average annual increase of over 184% from 2000 to 2006. This is a direct indication of the need for increased access to fixed MRI services. Clearly, special circumstances exist in Guilford County with regard to utilization of mobile MRI services that necessitate the need for additional fixed MRI access. GOC believes an adjusted need determination for one additional fixed MRI scanner in Guilford County will provide much needed local services that will be highly utilized.

Fixed MRI Scanners in Guilford County

In addition to having high utilization of MRI services, demographic data also demonstrates a clear need for increased access to fixed MRI services in Guilford County.

Currently, there are ten operational MRI scanners in Guilford County. This is disproportionate to the growing population in Guilford County. Comparatively, of the seven most populous counties in North Carolina, Guilford County has the second worst ratio of fixed MRI scanners to population. Please refer to the table below.

Fixed MRI Scanner to Population Ratio
Most Populous North Carolina Counties

County	2006 Population	2011 Population	% Change	Total Fixed Magnets	Magnet to Population Ratio
Wake	789,969	933,711	18.2%	11	71,815
Guilford	449,071	481,855	7.3%	10	44,907
Cumberland	306,545	314,202	2.5%	7	43,792
Mecklenburg	826,897	952,975	15.2	19	43,521
Forsyth	331,851	356,188	7.3%	14	23,704
Buncombe	221,327	238,214	7.6	10	22,133
Durham	246,825	266,860	8.1%	12	20,569

Source: Proposed 2008 SMFP, NC State Demographics (

Forsyth County (which is adjacent to Guilford County) has a far more favorable ratio of fixed MRI scanners to population. Notably, however, in 2006 Guilford County had a population 30% higher than that of Forsyth County. Also, Buncombe County, which has a population less than half that of Guilford County, has the same number of fixed MRI scanners (10) as Guilford County. Both of these examples are inconsistent with the principle of equitable access to healthcare services in North Carolina.

As the population continues to increase and the medical community continues to grow, there is no indication that the trending increase of MRI services in Guilford County will change in the near future.

Guilford County MRI Use Rate

Improved MRI technology and capabilities have enhanced the clinical diagnostic approaches to many illnesses and disease states. As a result, MRI is often the imaging modality of choice for an increasing number of conditions that local physicians seek to diagnose each day. As a result, MRI utilization rates have greatly increased. The North Carolina MRI utilization rate was 88.7 procedures per 1,000 population in 2006. In the last two years (2004-2006) the North Carolina MRI use rate increased by 30%.

MRI utilization rates for individual counties in North Carolina are trending upward as well. Residents of Guilford County and their physicians recognize the valuable benefits of MRI services. As a result, MRI services are highly utilized in Guilford County. The Proposed 2008 SMFP shows Guilford County as having a higher MRI use rate compared to the North Carolina average.

2006 MRI Use Rate per 1,000 Population

	MRI Procedures	Population	MRI Use Rate
Guilford County	52,235	449,071	116.3
North Carolina	786,150	8,860,341	88.7

Source: Proposed 2008 SMFP, NC State Demographics (http://demog.state.nc.us/) updated 2006.

As shown above, Guilford County provides MRI services over 31% above the State average. In fact, Guilford County has the 14th highest MRI use rate per 1,000 population of the 100 counties in North Carolina. Please refer to the table below.

2006 MRI Use Rates by County

County	# of Procedures			2006 Population	MRI Use Rate
	Fixed	Mobile	Total		
MOORE	12,704	6,664	19,368	82,288	235.4
ORANGE	25,610	--	25,610	123,762	206.9
FORSYTH	60,024	7,356	67,380	331,851	203.0
BUNCOMBE	40,405	156	40,561	221,327	183.3
DURHAM	43,735	1,290	45,025	246,825	182.4
PITT	24,554	843	25,397	146,398	173.5
HERTFORD	2,036	2,018	4,054	23,901	169.6
CHOWAN	--	2,438	2,438	14,677	166.1
CABARRUS	24,910	575	25,485	157,176	162.1
NEW HANOVER	16,292	10,362	26,654	184,116	144.8
CATAWBA	13,910	6,592	20,502	151,126	135.7
CRAVEN	12,181		12,181	95,566	127.5
IREDELL	16,850	308	17,158	145,232	118.1
GUILFORD	34,562	17,673	52,235	449,071	116.3

Source: Proposed 2008 SMFP, NC State Demographics (http://demog.state.nc.us/) updated 2006

Below is a table showing the North Carolina counties that had the most MRI scans during FY 2006. As shown, Guilford County hosted the 4th largest number of MRI scans of all 100 North Carolina counties.

Highest Volume MRI Counties in North Carolina

County	Fixed	Mobile	Total
MECKLENBURG	68,428	20,118	88,546
FORSYTH	60,024	7,356	67,380
WAKE	45,047	10,645	55,692
GUILFORD	34,562	17,673	52,235
DURHAM	43,735	1,290	45,025
BUNCOMBE	40,405	156	40,561
CUMBERLAND	28,410	383	28,793
NEW HANOVER	16,292	10,362	26,654
ORANGE	25,610	0	25,610
CABARRUS	24,910	575	25,485
PITT	24,554	843	25,397

Sources: 2008 SMFP

This is a clear indication that MRI is an important and highly utilized service for Guilford County.

In addition to being North Carolina's 3rd most populous county, Guilford County is also one of the State's primary health care centers. Guilford County hosts large medical centers, and is home to a large number of physicians and other provider professionals (such as Greensboro Orthopaedics), representing practically every medical specialty and sub-specialty. These providers serve not only residents of Guilford County, but also residents of neighboring counties and residents from throughout North Carolina and adjacent states. As a result, it is important that the county's resources have the capacity to accommodate this current and growing demand.

Further, of the 12 North Carolina counties for which the Proposed 2008 SMFP indicates a need determination for an additional fixed MRI scanner, nine counties have at least one fixed MRI scanner, and of those, six have a lower population to fixed MRI scanner ratio than does Guilford County. Please see the table below.

Proposed 2008 SMFP MRI Need Determination Counties

County	2006 Population	2011 Population	% Change	Total Fixed Magnets	Magnet to Population Ratio	Need Determination
Orange	123,762	131,195	6.0	7	17,680	1
Forsyth	331,851	356,188	7.3	14	23,704	1
Craven	95,566	99,884	4.5	3	31,855	1
Jackson	36,312	38,478	6.0	1	36,312	1
Surry	73,000	75,230	3.1	2	36,500	1
Vance	43,925	45,204	2.9	1	43,925	1
Guilford	449,071	481,855	7.3	10	44,907	0
Lenoir	58,170	57,910	-0.4	1	58,170	1
Carteret	63,557	66,856	5.2	1	63,557	1
Wilkes	66,924	68,130	1.8	1	66,924	1

Source: Proposed 2008 SMFP, NC State Demographics (http://demog.state.nc.us/) updated 2006

In addition, the percentage of Guilford County residents who obtain MRI scans in other counties has been steadily increasing the past three years. As shown on the table below, during FY2006 over 13% of Guilford County residents had to obtain an MRI scan outside the county. This represents a 45% increase from FY2003.

Out-of-county MRI Scans
Guilford County Residents
FY2003 - FY2005

Year	% of Total Scans
2003	9.1
2004	9.7
2005	13.1
2006	13.2

Source: MRI Patient Origin Data, Medical Facilities Planning Section

These data are a strong indication of the limited access to MRI services within Guilford County. In order to provide quality and timely care it is essential that Guilford County

have an inventory of fixed MRI scanners that is proportionate to the population seeking such services.

No Unnecessary Duplication of Services

Greensboro Orthopaedics has established that Guilford County currently has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties. This petition also contains evidence that a growing percentage of the MRI scans performed on Guilford County residents are obtained in another county. This provides further evidence that an additional fixed MRI scanner is needed in Guilford County. Also, members of the medical communities in Guilford County indicate that an additional fixed MRI scanner in the local community will increase access, alleviate capacity constraints on existing providers, and will better serve the community's MRI needs. Clearly therefore, addition of another fixed MRI scanner in Guilford County is not unnecessary duplication. Similarly, Guilford County had the second highest mobile utilization in FY2006 of all North Carolina counties. This is a direct indication of the need for increased access to fixed MRI services.

Adverse Effects of No Adjustment to the Need Determination

Should this petition not be granted, Guilford County would have to continue with the status quo. The existing fixed and mobile providers would continue providing the existing MRI services with their present inadequate capacity. However, given the steady increase of MRI utilization in Guilford County, this is not a viable alternative. The table below provides historical MRI utilization in Guilford County.

Guilford County Historical MRI Utilization
FY2001-FY2006

	MRI Procedures	% Increase
2001	40,489	21.1
2002	42,251	4.4
2003	46,244	9.5
2004	50,912	10.1

2005	53,569	5.2%
2006	52,235	-2.5%

Source: 2003 – 2007 SMFP, Proposed 2008 SMFP

In the past five years, Guilford County has experienced a total increase in MRI procedures of over 29%. As previously stated in this petition, the mobile MRI utilization has increased much faster, 184%, during the same five-year period. As a result, the proportion of mobile MRI scans performed in Guilford County has risen from 18% of total MRI scans in 2001, to nearly 34% of total MRI scans in 2006. Please see the table below.

Guilford County Mobile MRI Utilization Ratio

	Mobile Utilization	Total Utilization	% Mobile of Total
2000	6,217	33,428	18.6%
2001	8,905	40,489	22.0%
2002	11,058	42,251	26.2%
2003	13,194	46,244	28.5%
2004	14,680	50,912	28.8
2005	15,307	53,569	28.6
2006	17,673	52,235	33.8

Source: 2003 – 2007 SMFP, Proposed 2008 SMFP

As previously discussed, the ratio of fixed MRI providers to population is already less favorable than comparative and surrounding counties, and Guilford County currently has the second largest mobile MRI volume in the State. These factors combined make the status quo unacceptable from a planning and patient access perspective.

Since 1997, Greensboro Orthopaedics has provided mobile MRI services in Guilford County. Currently, a mobile MRI scanner is on site and operational five days each week. While Greensboro Orthopaedics values the services a mobile MRI scanner provides to the community, it is not the most effective option from an operational, patient, or cost perspective. First, reliability is not equivalent to that of fixed scanners. Each year, GOC experiences several days when its mobile MRI scanner is down or due to

factors associated with travel of the mobile unit. This results in an unnecessary delay of patient access to MRI services. Second, physical access to mobile service is less than ideal, because mobile MRI scanners are physically located outside a facility on a concrete pad. Access to mobile MRI scanners can be especially problematic in inclement weather, or during days of extreme hot or cold temperatures. This creates an unnecessary burden for patients, especially the elderly or patients already in pain.

Existing providers of mobile MRI services in Guilford are reaching practical operating capacity. For example, Greensboro Orthopaedic's mobile MRI utilization, although the highest in the county, has been relatively flat for the last two years, compared to the growth in previous years.

Greensboro Orthopaedics, P.A.
Mobile MRI Utilization
FY2001-FY2006

Year	MRI Scans	% Increase
FY2001	2,646	--
FY2002	4,238	60.2
FY2003	4,582	8.1
FY2004	5,128	11.9
FY2005	5,288	3.1
FY2006	5,526	4.5

Source: 2005-2007 SMFPs, Proposed 2008 SMFP

This is due to the high utilization of mobile MRI services at Greensboro Orthopaedics, and the lack of additional capacity. As stated previously, GOC has operational access to a mobile MRI scanner five days each week. Due to the current utilization of its existing mobile MRI services and the amount downtime experienced each year, GOC is not able to accommodate the demand for its MRI services. GOC's experience is not unusual as mobile MRI capacity is limited throughout the State.

Finally, there are negative cost implications associated with maintaining the status quo in Guilford County. As described previously, Guilford County performed the greatest number of mobile MRI procedures in North Carolina in 2006 (17,673 mobile MRI procedures). Hospitals and freestanding facilities that host mobile MRI scanners experience higher costs due to the fee that must be paid to the mobile provider for each

MRI scan. Unfortunately, these higher costs are often transmitted to the patients. As a current provider of mobile MRI services, GOC estimates that, on average in Guilford County, approximately $300 per scan is paid to the mobile MRI provider. Thus, in FY2006, this equates to approximately $5,302,000 in fees that were paid to mobile providers in Guilford County. These costs are passed along to consumers.

Mobile MRI scanners provide a valuable service to Guilford County, however, it is not the most cost effective alternative for patients. If an adjusted need determination is not granted for Guilford County, patients and providers will continue to experience increased charges and costs, respectively.

Conclusion:

In summary, Greensboro Orthopaedics, P.A. seeks an adjusted need determination to include one fixed MRI scanner in Guilford County in the 2008 SMFP, based on the following reasons:

- The MRI utilization in Guilford County is well above the State's average use rate.
- Guilford County has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties.
- Guilford County had the second highest mobile utilization in FY2006 of all North Carolina counties, and its proportion of mobile MRI scans to total MRI scans is increasing.
- Of the 12 counties with fixed MRI need determinations in the proposed 2008 SMFP, nine have a lower population to fixed MRI ratio than does Guilford County.
- The percentage of Guilford County residents who obtain MRI scans in other counties has been steadily increasing the past three years.
- Because of the high level of mobile MRI utilization in Guilford County, the lack of a need determination for an additional fixed MRI scanner in Guilford County has negative cost implications for patients and providers, thus adversely effects this population.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

We feel there is a clear need for an additional fixed MRI scanner in Guilford County. We hope you will support us in this effort by approving this petition for an adjusted

need determination. Thank you for providing us with the opportunity to present this important community issue.

Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Comments – 3: Greensboro Orthopaedics, P.A.

Greensboro PH
7-20-07
MRI
Tom

Medical Facilities
Planning Section

SHCC Public Hearing Presentation Comments for
Adjusted Need Determination for Fixed MRI Scanners in Guilford County
July 20, 2007

Good afternoon, my name is David Meyer. I am a consultant to Greensboro Orthopaedics. I am here today to speak on behalf of their petition for an adjusted need determination for one fixed MRI scanner in Guilford County to be included in the 2008 State Medical Facilities Plan.

Approval of this petition will enable any eligible applicant the opportunity to submit competitive Certificate of Need applications proposing the best plan for addition of a fixed MRI scanner in Guilford County.

There are a number of reasons that justify an adjusted need determination in Guilford County:

Historically, mobile MRI utilization has played an important role in determining need for fixed MRI scanners in Guilford County. Mobile utilization in Guilford County triggered a need for a fixed MRI scanner in the 2001, 2002, 2003 and 2005 SMFPs.

Currently, Guilford County has four MRI providers that are exclusively mobile sites. In FY2006, these four providers performed 11,988 mobile MRI procedures. In addition, three other mobile MRI host sites performed an additional 5,685 mobile MRI procedures. This is the second highest utilization of mobile MRI services of any county in the State. The scans performed at these sites are indicative of a greater need for at least another fixed MRI scanner based in Guilford County. Clearly, special circumstances exist in Guilford County with regard to utilization of mobile MRI services that necessitate the need for additional fixed MRI access.

Second, Guilford County has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties. Specifically, of the seven most populous counties in North Carolina (counties with populations exceeding

days when its mobile MRI scanner is down due to factors associated with travel of the mobile unit. This results in an unnecessary delay of patient access to MRI services. Additionally, physical access to mobile service is less than ideal, because mobile MRI scanners are physically located outside a facility on a concrete pad. Physical access to mobile MRI scanners can be especially problematic in inclement weather, or during days of extreme hot or cold temperatures. This creates an unnecessary burden for patients, especially the elderly or patients already in pain.

In summary, Greensboro Orthopaedics seeks an adjusted need determination to include one fixed MRI scanner in Guilford County in the 2008 SMFP, based on the following reasons:

- Guilford County had the second highest mobile utilization in FY2006 of all North Carolina counties.
- Guilford County has an unreasonably low ratio of fixed MRI scanners to population compared to other similar counties.
- The MRI utilization in Guilford County is well above the State's average use rate.
- Of the 12 counties with fixed MRI need determinations in the proposed 2008 SMFP, nine have a lower population to fixed MRI ratio than does Guilford County.
- Because of the high level of mobile MRI utilization in Guilford County, the lack of a need determination for an additional fixed MRI scanner in Guilford County has negative cost implications for patients and providers, thus adversely effects this population.
- Mobile MRI services are not the most effective option from an operational or patient perspective.

We feel there is a clear need for an additional fixed MRI scanner in Guilford County. We hope you will support us in this effort by approving this petition for an adjusted need determination. Thank you for providing us with the opportunity to discuss this important issue.

Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Petition – 4: HOPE, A Women's Cancer Center

Hope
A Women's Cancer Center

PETITION FOR AN ADJUSTED NEED DETERMINATION FOR DEDICATED BREAST MRI SCANNER FOR HSA I

Petitioner:

Hope – A Women's Cancer Center
100 Ridgefield Court
Asheville, NC 28806
(828) 670-8403

David J. Hetzel M.D., FACOG, FACS
Nathan Williams, M.D., FACS
Tim Vanderkwaak, M.D., FACOG, FACS
C. Blair Harkness, M.D., FACOG

Requested Change:

Hope – A Women's Cancer Center is dedicated to providing the finest Gynecologic and Breast Oncology services in western North Carolina and petitions for an adjusted need determination for one Dedicated Breast MRI scanner for HSA I in the 2008 SMFP.

Reasons Supporting Requested Change:

Breast cancer is the most common cancer among women. Every three minutes a woman in the United States is diagnosed with breast cancer. In 2006, an estimated 212,920 new cases of invasive breast cancer are expected to be diagnosed, along with 61,980 new cases of non-invasive breast cancer. And

40,970 women are expected to die in 2006 from this disease[1]. This risk has increased dramatically over the past four decades. Today the chance of developing invasive breast cancer at some time in a woman's life is about 1 in 7. In 1960, the chance of developing invasive breast cancer was only 1 in 20. Women living in North America have the highest rate of breast cancer in the world[2].

The North Carolina Central Cancer Registry (NCCCR) projected that 6,335 women in North Carolina would be diagnosed with breast cancer in 2005. In HSA I the NCCCR projects 1,140 breast cancer cases or almost 18% of the total North Carolina breast cancer cases in 2005[3].

For breast cancer, early detection saves lives. For example, almost 98 percent of women who are diagnosed with breast cancer in the earliest stage survive the disease, whereas only 26 percent survive if the disease is diagnosed in the most advanced stage. The opportunity for disease control and for reducing the number of cancer deaths rests with prevention and early detection so that treatment of the disease can be effective. This is the foundation of our petition for a dedicated breast MRI scanner in HSA I.

Hope is aware that the 2006 State Medical Facilities Plan included an adjusted need determination for a dedicated and specialized breast MRI scanner. This adjusted need determination was the result of a petition submitted by Novant Health in Winston-Salem. This petition was based on American Cancer Society (ACS) Guidelines that were released in 2003 stating women might benefit from additional screening strategies beyond those offered to women at average risk.

The evidence that was available at the time of the 2003 ACS Guidelines was insufficient to justify recommendations for additional screening approaches, such as MRI. The ACS recommended that decisions about screening options for women at significantly increased risk of breast cancer be based on shared decision making after a review of potential benefits, limitations, and harms of different screening strategies and the degree of uncertainty about each.

Nonetheless, the State Health Coordinating Council (SHCC) and North Carolina Division of Health Service Regulation (DHSR) staff determined that expanding dedicated breast MRI imaging in the State could be important. The Breast Clinic MRI, LLC (Forsyth County, HSA II) was awarded a CON for the dedicated breast MRI scanner; that project is currently under development.

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[1] www.breastcancer.org
[2] American Cancer Society
[3] North Carolina Central Cancer Registry, 2005 Profiles

New evidence on breast MRI screening has become available since the ACS last issued guidelines in 2003. A guideline panel has reviewed this evidence and developed new recommendations for women at different levels of risk.

According to the ACS, women with a genetic predisposition to breast cancer, and/or those with a family history of the disease, should undergo annual MRI screening along with routine mammograms. Specific guidelines were released in March of 2007 identifying the women who should have a breast MRI scan. These guidelines include:

- Those who are BRCA mutation carriers;
- Women with first-degree relatives who are BRCA mutation carriers;
- Women with a 20% to 25% lifetime risk of breast cancer based on family history;
- Women who had radiation treatment to the chest between the ages of 10 and 30; and
- Women with Li-Fraumeni, Cowden, or Bannayan-Riley-Ruvalcaba syndromes[4].

The guideline states that, for high-risk women, screening with MRI and mammography should begin at age 30. These new guidelines demonstrate that a much larger population can benefit from breast MRI screening compared to the 2003 guidelines. A copy of the ACS report has been included with this petition. Based on the 2007 ACS guidelines, geography and demographic data, need for a local dedicated breast MRI scanner is strongly indicated to most appropriately serve residents of HSA I.

As stated previously, one guideline for identifying women who should have a breast MRI scan are those who are BRCA mutation carriers. The prevalence of BRCA mutations is estimated to be between 1/500 and 1/100 in the general population[4]. This equates to approximately 445 Buncombe County residents and over 2,700 women in HSA I who could benefit from an annual breast MRI scanner. Please refer to the table below.

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[4] Saslow et al for the American Cancer Society Breast Cancer Advisory Group. American Cancer Society Guidelines with MRI as an Adjunct to Mammography. CA Cancer J Clin 2007; 57:75-89
Petruccelli N, Daly MB, Culver JOB, et al. BRCA1 and BRCA2 Hereditary Breast/Ovarian Cancer. Gene Reviews. December 28, 2006.

2007 Estimated BRCA Mutation Carriers - HSA I

	2007
ALLEGHANY	22
ASHE	51
WATAUGA	87
WILKES	137
AVERY	37
ALEXANDER	73
CALDWELL	159
MITCHELL	33
BURKE	180
CATAWBA	307
YANCEY	37
MCDOWELL	89
CLEVELAND	198
RUTHERFORD	128
MADISON	41
BUNCOMBE	445
HENDERSON	203
POLK	39
HAYWOOD	117
TRANSYLVANIA	60
SWAIN	28
JACKSON	75
GRAHAM	16
MACON	67
CHEROKEE	54
CLAY	20
HSA I Total Population	**2,703**

Source: 2007 population provided by NC Office of State Budget and Management / 500

The 2007 ACS Guidelines also state that women with a 20% to 25% lifetime risk of breast cancer based on family history should have an annual breast MRI scan. According to the American Cancer Society, 2% of women have a family history suggestive of breast cancer inheritance. While 2% may sound nominal, this equates to as many as 2,337 women in Buncombe County and 13,747 women in HSA I. Please refer to the following table.

Women with 20% to 25% Lifetime Risk of Breast Cancer Based on Family History 2007 Population, HSA I

	2007
ALLEGHANY	112
ASHE	261
WATAUGA	436
WILKES	678
AVERY	166
ALEXANDER	368
CALDWELL	805
MITCHELL	161
BURKE	885
CATAWBA	1,541
YANCEY	189
MCDOWELL	438
CLEVELAND	1,000
RUTHERFORD	654
MADISON	209
BUNCOMBE	2,337
HENDERSON	1,049
POLK	201
HAYWOOD	593
TRANSYLVANIA	322
SWAIN	148
JACKSON	375
GRAHAM	84
MACON	351
CHEROKEE	280
CLAY	106
HSA I Total Population	**13,747**

Source: NC Office of State Budget and Management

Based on only two of the 2007 ACS Guidelines, approximately 16,450 women in HSA I are indicated for an annual breast MRI scan. The 2007 ACS Guidelines also recommend annual breast MRI screening for women with first-degree relatives who are BCRA mutation carriers, women who had radiation treatment to the chest between the ages of 10 and 30 and women with Li-Fraumeni, Cowden, or Bannayan-Riley-Ruvalcaba syndromes. Clearly, need exists for increased access to convenient breast MRI imaging in western North Carolina.

In addition to the 2007 ACS Guidelines, a March 2007 study in the New England Journal of Medicine (NEJM) indicates that for women who have newly diagnosed cancer in one breast, MRI can find tumors in the other breast that mammograms miss. Even after careful clinical and mammographic evaluation, cancer is found in the contra lateral breast in up to 10% of women who have received treatment for unilateral breast cancer[5]. The study, conducted at 25 medical centers, included 969 women with recently diagnosed cancer in one breast and a normal mammogram on the other. All were given MRI scans, which discovered cancers in the supposedly healthy breast in 30 women, 3.1 percent of the group. Nearly all cancers were at an early stage, and were treated at the same time as the cancers that were originally discovered. Thus, breast MRI can help women who already have one cancer by detecting a hidden tumor in the other breast, enabling them to have both cancers treated at once instead of having to go through treatment all over again when the second tumor is finally detected. MRI can also be used to evaluate the rest of the breast tissue prior to a lumpectomy to detect whether the cancer has spread.

The ACS states "there are substantial concerns about limited access to high-quality MRI breast screening services for women with familial risk. With many communities not providing MRI screening, it is recognized that these recommendations may generate concerns in high-risk women who may have limited access to this technology."

Based on the 2007 SMFP, residents of HSA II currently have local access to dedicated breast MRI services in Charlotte. Residents in HSA III will have soon have local access to dedicated breast MRI services in Winston-Salem pursuant to the 2006 SMFP adjusted need determination and subsequently approved CON for The Breast Clinic MRI, LLC. Residents of HSA I do not have local access to dedicated breast MRI services. It is well known that it is very difficult for residents of western North Carolina to travel long distances for healthcare services. Furthermore, the 2007 ACS Guidelines identify a greater population of women who can benefit from breast MRI (the 2003 ACS data were merely recommendations). A dedicated breast MRI scanner is needed in HSA I to serve the residents of western North Carolina.

Some data is available on the cost-effectiveness of breast MRI screening. One recent study modeled cost-effectiveness for adding MRI to mammography screening for women of different age groups who carry a BRCA1 or BRCA2 mutation. The authors concluded that the cost per quality-adjusted life year

[5] Lehman et al. MRI Evaluation of the Contralateral Breast in Women with Recently Diagnosed Breast Cancer. New England Journal of Medicine Volume 356:1295-1303 March 29, 2007 Number 13

saved for annual MRI plus film mammography, compared with annual film mammography alone, varied by age and was more favorable in carriers of a mutation in BRCA1 than BRCA2 because BRCA1 mutations confer higher cancer risk and higher risk of more aggressive cancers, than BRCA2 mutations[6]. Estimated cost per quality of life year for women aged 35 to 54 years was $55,420 for women with BRCA1 mutation and $130, 695 for women with BRCA2 mutation.

The ACS states that the ability of MRI to detect breast cancer is directly related to high-quality imaging, particularly the signal-to-noise-ratio, as well as spatial resolution of the MRI image. Thus, it is necessary to implement local dedicated breast MRI technology in HSA I to serve western North Carolina residents. The existing, general purpose MRI scanners currently in HSA I are not sufficient to provide the benefits of dedicated breast MRI screening. Specifically, the ability to perform MRI-guided biopsy is absolutely essential to offering screening MRI[7]. The American College of Radiology (ACR) is currently developing an accreditation process for performing breast MRI, and, in addition to the performance of high spatial resolution images, the ability to perform MRI intervention (i.e. needle localization and/or biopsy) will be essential in order to obtain accreditation by ACR. This guideline will likely be available in 2007.

Hope currently has resources in place to effectively provide dedicated breast MRI services. Hope is a skilled women's cancer center, experienced in treating women with cancer such as breast, ovarian, and cervical cancer. Hope has provided women's healthcare services to patients of western North Carolina for over 14 years. Hope currently provides an array of diagnostic services for its patients, including mammography, stereotactic breast biopsy, chest X-ray, bone densitometry, and ultrasound.

Hope physicians are primary investigators for the Gynecologic Oncology Group in western North Carolina. The GOG is the primary study group for women's cancers in the United States. Hope is also a cooperative group with the American College of Surgeons - Oncology Group and participates in breast cancer trials. In addition Hope participates in other clinical trials through Cancer Trials Support Unit which is a clearinghouse to facilitate enrollment in clinical trials that are sponsored by other cooperative groups. The National Cancer Institute (NCI) works with the GOG, other cooperative groups and most of the major cancer centers to develop new treatments or fine-tuning existing ones.

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[6] Antoniou A, Pharoah PD, Narod S, et al. Average risks of breast and ovarian cancer associated with BRCA1 or BRCA2 mutations detected in case series unselected for family history: a combined analysis of 22 studies. Am J hum Genet 2003; 72:1117-1130.

[7] Saslow et al for the American Cancer Society Breast Cancer Advisory Group. American Cancer Society Guidelines with MRI as an Adjunct to Mammography. CA Cancer J Clin 2007; 57:75-89

These changes usually lead to improving the standard of care. In short, Hope, with its clinical research program dedicated to the advancement of women's cancer care through clinical research and education, is an ideal location for implementation of dedicated breast MRI technology.

Adverse Effects on the Population if the Adjustment for a Dedicated Breast MRI Scanner is Not Made

If this petition for an adjusted need determination for a dedicated breast MRI scanner in HSA I is not granted, residents of western North Carolina will be denied local access to state-of-the-art technology that is proven to be beneficial for a specific patient population. This petition identifies at least 16,450 western North Carolina residents who can benefit from this technology, according to the 2007 ACS Guidelines.

In addition, failure to approve this petition will deprive the estimated 1,140 women[8] who have newly diagnosed cancer in one breast, the opportunity to readily identify tumors in the other breast that mammograms miss.

Lives could be saved and treatment courses modified through the use of breast MRI scans to detect breast cancer more accurately. Failure to allow the implementation of this technology in HSA I may increase long-term health costs, because existing modalities are less likely to detect cancer compared to MRI.

No Unnecessary Duplication of Services

Approving this petition will not result in any unnecessary duplication of services in HSA I. As stated previously, residents of western North Carolina do not have timely and convenient access to local dedicated breast MRI services. Additionally, the ACS Guidelines stress the ability of MRI to detect breast cancer is directly related to high-quality imaging, particularly the signal-to-noise-ratio, as well as spatial resolution of the MRI image. Additionally, the ability to perform MRI-guided biopsy is absolutely essential to offering screening MRI. General purpose MRI scanners do not offer this technology. Thus, it is necessary to implement dedicated breast MRI technology in HSA I to serve western North Carolina residents. The existing, general purpose MRI scanners currently in HSA I are not sufficient to provide the benefits of dedicated breast MRI screening.

[8] North Carolina Central Cancer Registry estimated 2005 cancer cases in HSA I.

Conclusion

In summary, Hope – A Women's Cancer Center seeks an adjusted need determination in the 2008 SMFP to include one dedicated breast MRI scanner for HSA I, based on the following reasons:

- The 2007 ACS Guidelines identify specific groups of women who should have a breast MRI scan.
- Hope identifies at least 16,450 western North Carolina residents who can benefit from this technology, according to the 2007 ACS Guidelines.
- The New England Journal of Medicine indicates that for women who have newly diagnosed cancer in one breast, MRI can find tumors in the other breast that mammograms miss.
- The ability of MRI to detect breast cancer is directly related to high-quality imaging, particularly the signal-to-noise-ratio, as well as spatial resolution of the MRI image.
- Residents of western North Carolina do not have local access to dedicated breast MRI services.
- Failure to allow the implementation of this technology in HSA I may increase long-term health costs, because existing modalities are less likely to detect cancer compared to MRI.
- Hope already has resources in place, including stereotactic breast biopsy, to effectively provide dedicated breast MRI services.

CA Cancer J Clin 2007; 57:75-89

American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography

**Debbie Saslow, PhD,
Carla Boetes, MD, PhD,
Wylie Burke, MD, PhD,
Steven Harms, MD,
Martin O. Leach, PhD,
Constance D. Lehman, MD, PhD,
Elizabeth Morris, MD, Etta Pisano, MD,
Mitchell Schnall, MD, PhD,
Stephen Sener, MD,
Robert A. Smith, PhD, Ellen Warner, MD,
Martin Yaffe, PhD, Kimberly S. Andrews,
Christy A. Russell, MD for the American Cancer Society Breast Cancer Advisory Group**

Dr. Saslow is Director, Breast and Gynecologic Cancer, Cancer Control Science Department, American Cancer Society, Atlanta, GA
Dr. Boetes is Professor, Department of Radiology, University Medical Center Nijmegen, Nijmegen, The Netherlands
Dr. Burke is Chair, and Professor of Medical History and Ethics, University of Washington, Seattle, WA
Dr. Harms is Radiologist, The Breast Center of Northwest Arkansas, Fayetteville, AR, and Clinical Professor of Radiology, University of Arkansas for Medical Sciences, Little Rock, AR
Dr. Leach is Professor of Physics as Applied to Medicine, Co-Chairman, Section of Magnetic Resonance, and Co-Director, Cancer Research, UK Clinical Magnetic Resonance Research Group, The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust, Surrey, UK
Dr. Lehman is Professor of Radiology, and Section Head of Breast Imaging, University of Washington Medical Center and the Seattle Cancer Care Alliance, Seattle, WA
Dr. Morris is Director, Breast MRI, Department of Radiology, Memorial Sloan-Kettering Cancer Center, New York, NY
Dr. Pisano is Vice Dean for Academic Affairs; Kenan Professor of Radiology and Biomedical Engineering, and Director, UNC Biomedical Research Imaging Center, UNC School of Medicine, University of North Carolina, Chapel Hill, NC
Dr. Schnall is Matthew J. Wilson Professor of Radiology; and Associate Chair for Research, Department of Radiology, University of Pennsylvania, Philadelphia, PA
Dr. Sener is Vice Chairman, Department of Surgery, Evanston Northwestern Health Care, Evanston, IL, and Professor of Surgery, Northwestern University Feinberg School of Medicine, Chicago, IL
Dr. Smith is Director, Cancer Screening, Cancer Control Science Department, American Cancer Society, Atlanta, GA
Dr. Warner is Associate Professor, Department of Medicine, University of Toronto and Toronto-Sunnybrook Regional Cancer Centre, Toronto, Canada
Dr. Yaffe is Senior Scientist, Imaging Research, Sunnybrook Health Sciences Centre, and Professor, Departments of Medical Imaging and Medical Biophysics, University of Toronto, Toronto, Canada
Ms. Andrews is Research Associate, Cancer Control Science Department, American Cancer Society, Atlanta, GA
Dr. Russell is Associate Professor of Medicine, Keck School of Medicine, University of Southern California, and Co-Director of USC/Norris Breast Center, Los Angeles, CA

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ABSTRACT

New evidence on breast Magnetic Resonance Imaging (MRI) screening has become available since the American Cancer Society (ACS) last issued guidelines for the early detection of breast cancer in 2003. A guideline panel has reviewed this evidence and developed new recommendations for women at different defined levels of risk. Screening MRI is recommended for women with an approximately 20 25% or greater lifetime risk of breast cancer, including women with a strong family history of breast or ovarian cancer and women who were treated for Hodgkin disease. There are several risk subgroups for which the available data are insufficient to recommend for or against screening, including women with a personal history of breast cancer, carcinoma in situ, atypical hyperplasia, and extremely dense breasts on mammography. Diagnostic uses of MRI were not considered to be within the scope of this review.

INTRODUCTION

Mammography has been proven to detect breast cancer at an early stage and, when followed up with appropriate diagnosis and treatment, to reduce mortality from breast cancer. For women at increased risk of breast cancer, other screening technologies also may contribute to the earlier detection of breast cancer, particularly in women under the age of 40 years for whom mammography is less sensitive. The American Cancer Society (ACS) guideline for the early detection of breast cancer, last updated in 2003, stated that women at increased risk of breast cancer might benefit from additional screening strategies beyond those offered to women at average risk, such as earlier initiation of screening, shorter screening intervals, or the addition of screening modalities (such as breast ultrasound or magnetic resonance imaging [MRI]) other than mammography and physical examination. However, the evidence available at the time was insufficient to justify recommendations for any of these screening approaches. The ACS recommended that decisions about screening options for women at significantly increased risk of breast cancer be based on shared decision making after a review of potential benefits, limitations, and harms of different screening strategies and the degree of uncertainty about each.[1]

Although there still are limitations in the available evidence, additional published studies have become available since the last update, particularly regarding use of breast MRI. The ACS guideline panel has sought to provide additional guidance to women and their health care providers based on these new data.

GUIDELINE DEVELOPMENT

The ACS convened an expert panel to review the existing early detection guideline for women at increased risk and for MRI screening based on evidence that has accumulated since the last revision in 2002 to 2003. Literature related to breast MRI screening published between September 2002 and July 2006 was identified using MEDLINE (National Library of Medicine), bibliographies of identified articles, and unpublished manuscripts. Expert panel members reviewed and discussed data during a series of conference calls and a working meeting in August, 2006. When evidence was insufficient or lacking, the final recommendations incorporated the

expert opinions of the panel members. The ACS Breast Cancer Advisory Group members and the National Board of Directors discussed and voted to approve the recommendations.

SUMMARY OF RECOMMENDATIONS

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Table 1 summarizes the ACS recommendations for breast MRI screening.

View this table: TABLE 1 Recommendations for Breast MRI Screening as an Adjunct to Mammography
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BACKGROUND

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MRI

MRI utilizes magnetic fields to produce detailed cross-sectional images of tissue structures, providing very good soft tissue contrast. Contrast between tissues in the breast (fat, glandular tissue, lesions, etc.) depends on the mobility and magnetic environment of the hydrogen atoms in water and fat that contribute to the measured signal that determines the brightness of tissues in the image. In the breast, this results in images showing predominantly parenchyma and fat, and lesions, if they are present. A paramagnetic small molecular gadolinium-based contrast agent is injected intravenously to provide reliable detection of cancers and other lesions. Thus, contrast enhanced MRI has been shown to have a high sensitivity for detecting breast cancer in high-risk asymptomatic and symptomatic women, although reports of specificity have been more variable.[2-8] This high signal from enhancing lesions can be difficult to separate from fat, leading to the use of subtraction images or fat suppression, or both, to assess disease. Because parenchymal tissue also enhances, but generally more slowly than malignant lesions, and also because contrast can wash out rapidly from some tumors, it is important to look at images at an early time point after contrast injection (typically 1 to 3 minutes). MRI examinations may involve examining images at one time point or, more often, will collect a preinjection image with sequential sets of images after contrast injection (dynamic contrast-enhanced [DCE]-MRI). Both the appearance of lesions and, where available, the uptake and washout pattern can be used to identify malignant disease and discriminate it from benign conditions.

These techniques, which have been widely employed for assessing symptomatic disease, have recently been shown to provide good sensitivity as a screening tool for breast cancer in women at increased risk based on family history.[9-14] The approach requires appropriate techniques and equipment, together with experienced staff. Higher quality images are produced by dedicated breast MRI coils, rather than body, chest, or abdominal coils.

IDENTIFICATION OF WOMEN WITH A HIGH RISK OF BREAST CANCER

Three approaches are available for identifying women with a high risk of breast cancer: family history assessment, genetic testing, and review of clinical history. All contribute to identifying women who are candidates for breast MRI screening.

Family History

Although a high proportion of women in the general population have at least one relative with breast cancer, for the majority of these women, this "family history" either does not increase risk at all (ie, the cancer was sporadic) or is associated with, at most, a doubling of lifetime risk (due to either shared environmental risk factors or an inherited gene of low penetrance). Only 1% to 2% of women have a family history suggestive of the inheritance of an autosomal dominant, high-penetrance gene conferring up to an 80% lifetime risk of breast cancer. In some families, there is also a high risk of ovarian cancer. Features of the family history which suggest the cancers may be due to such a high-penetrance gene include 2 or more close (generally first- or second-degree) relatives with breast or ovarian cancer; breast cancer occurring before age 50 years (premenopausal) in a close relative; a family history of both breast and ovarian cancer; one or more relatives with 2 cancers (breast and ovarian cancer or 2 independent breast cancers); and male relatives with breast cancer.[15–18]

Two breast/ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, have been identified.[19,20] Inherited mutations in these genes can be found in approximately 50% of families in which an inherited risk is strongly suspected based on the frequency and age of onset of breast cancer cases, and in most families in which there is a much higher than expected incidence of both breast and ovarian cancer.

Several models can assist clinicians to estimate breast cancer risk or the likelihood that a *BRCA* mutation is present (Online Supplemental Material). The Gail, Claus, and Tyrer-Cusick models estimate breast cancer risk based on family history, sometimes in combination with other risk factors, such as reproductive history or prior breast biopsies.[16,21–23] Although risk prediction is generally similar for the different models, an individual woman's risk estimate may vary with different models.[21,24,25]

Two decision models have been developed to estimate the likelihood that a *BRCA* mutation is present, BRCAPRO[18,26] and the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA)[27]; the BOADICEA model also provides estimates of breast cancer risk (Online Supplemental Material).

Genetic Testing

The prevalence of *BRCA* mutations is estimated to be between 1/500 and 1/1,000 in the general population[28]; however, in women of Jewish ethnicity, the prevalence is 1/50.[29,30] Women with cancer-predisposing mutations in either *BRCA1* or *BRCA2* have an increased risk of both breast and ovarian cancer. From population-based studies, women with *BRCA1* mutations are estimated to have a 65% risk by age 70 years for developing breast cancer (95% confidence interval [CI], 44% to 78%); the corresponding risk for *BRCA2* mutations is 45% (95% CI, 31% to 56%).[31] Risks estimated from cancer-prone families seen in referral centers are higher, with limit of risk in the 85% to 90% range.[31] These mutations follow an autosomal dominant pattern of transmission, which means that the sister, mother, or daughter of a woman with a *BRCA* mutation has a 50% chance of having the same mutation.

The benefits and risks of genetic testing are beyond the scope of this article, but are reviewed in the American Society of Clinical Oncology policy statement update on genetic testing for cancer susceptibility.[32] Genetic testing for a *BRCA1* or *BRCA2* mutation is generally offered to adult members of families with a known *BRCA* mutation, or to women with at least a 10% likelihood of carrying such a mutation, based on either validated family history criteria or one of the above-mentioned models. If a woman from a family in which a *BRCA* mutation has been previously identified does not have that mutation, one can generally safely conclude that her breast cancer risk is no

higher than it would have been if she did not have a family history of breast cancer. However, in a high-risk family without a known mutation, failure to find a mutation in a particular member does not reduce her risk estimate.

A high risk of breast cancer also occurs with mutations in the *TP53* gene (Li-Fraumeni syndrome) and the *PTEN* gene (Cowden and Bannayan-Riley-Ruvalcaba syndromes).[33] Accurate prevalence figures are not available, but these conditions appear to be very rare.[34,35]

Clinical Indicators of Risk

Some clinical factors are associated with substantial breast cancer risk. Among women with Hodgkin disease, increased breast cancer risk has been consistently and significantly associated with mantle field radiation treatment. In several studies of women treated between 1955 and 1995, risk was inversely related to age at treatment in patients diagnosed between the ages of 10 to 30 years, with only slight or no increased risk when diagnosis was before age 10 years or after age 30 years.[36-41] Risk following treatment with radiation and chemotherapy was half that of treatment with radiation alone in two studies,[39,42] which may reflect the effect of chemotherapy on earlier onset of menopause; risk was equivalent in a third study.[43] Risk of breast cancer significantly increased 15 to 30 years after radiation therapy.[41] More recently, treatment approaches have used lower doses of radiation and limited-field radiotherapy. In one study, which compared patients who received radiation therapy in 1966 to 1974 and 1975 to 1985, treatment in the later timeframe was not related to increased risk of breast cancer after a median follow up of 13 years, whereas patients treated between 1966 and 1974 were at increased risk, suggesting that Hodgkin disease survivors treated with current approaches will not face substantially increased breast cancer risk.[44]

Lobular carcinoma in situ (LCIS) and atypical lobular hyperplasia (ALH), together described as lobular neoplasia, are associated with substantially increased risk of subsequent breast cancer, with lifetime risk estimates ranging from 10% to 20%.[45] This equates to a continuous risk of about 0.5% to 1.0% per year. The invasive cancers may be ipsilateral or contralateral, are usually invasive lobular cancers, and more than 50% of these diagnoses occur more than 15 years after the original diagnosis of LCIS. Similar findings have been reported by Fisher et al,[46] describing a 12-year update of 180 women with LCIS who were treated with local excision alone and followed by the National Surgical Adjuvant Breast Project (NSABP), as well as Li et al, who described the risk of invasive breast cancer among 4,490 LCIS patients using Surveillance, Epidemiology, and End Results (SEER) data between 1988 to 2001.[47]

Atypical ductal hyperplasia (ADH) is part of the continuum of ductal proliferative breast diseases ranging from usual ductal hyperplasia to ductal carcinoma in situ (DCIS). The literature review by Arpino et al[45] suggests a 4- to 5-fold increased risk of invasive breast cancer (compared with a 6- to 10-fold risk with LCIS) at a median follow up of 17 years, which is doubled if the woman has an associated family history of breast cancer. It is unclear, however, what percentage of the women with this family history and ADH are at this significantly increased risk because they are carriers of a *BRCA1* or 2 gene mutation.

Mammographic density has been shown to be a strong independent risk factor for the development of breast cancer.[48-51] In several studies, women with the most breast density were found to have a 4- to 6-fold increased risk of breast cancer, compared with women with the least dense breasts.[52-56] For example, women with 75% or higher mammographic density had a more than five-fold increased risk of breast cancer, compared with women with less than 1% density.[57] In addition, it has been shown that malignant tumors of the breast are more likely to arise in the areas of greatest mammographic density, compared with the more fatty areas of the breast.[58]

The absolute risk of contralateral breast cancer in women with a personal history of breast cancer is estimated to be 0.5% to 1% per year, or 5% to 10% during the 10 years following diagnosis, significantly higher than that of the general population.[59] Hormone therapy and or chemotherapy for the primary cancer is likely to subsequently lower the risk of contralateral breast cancer.

EVIDENCE AND RATIONALE

Evidence of Efficacy from MRI Screening Studies

In the mid to late 1990s, at least 6 prospective, nonrandomized studies were initiated in The Netherlands, the United Kingdom (UK), Canada, Germany, the United States (US), and Italy to determine the benefit of adding annual MRI to (film) mammography for women at increased risk of breast cancer. Some of the studies included ultrasound and/or clinical breast examination, as well. Despite substantial differences in patient population (age, risk, etc.) and MRI technique, all reported significantly higher sensitivity for MRI compared with mammography (or any of the other modalities). All studies that included more than one round of screening reported interval cancer rates below 10%. Participants in each of these 6 studies had either a documented *BRCA1* or *BRCA2* mutation or a very strong family history of breast cancer. Some of the studies included women with a prior personal history of breast cancer.

Kriege et al screened 1,909 unaffected women aged 25 to 70 years with an estimated 15% or higher lifetime risk of breast cancer (19% proven to have a *BRCA* mutation) at 6 centers across The Netherlands.[9] After a median of 3 rounds of screening, 50 breast cancers (44 invasive) were diagnosed. Eighty percent of the invasive cancers were detected by MRI, compared with 33% by mammography. However, mammography outperformed MRI for detecting DCIS. Of the invasive cancers, 43% were 1 cm or smaller in diameter, and 33% had spread to axillary lymph nodes. The specificity of MRI was 90%, compared with 95% for mammography.

Leach et al screened 649 unaffected women aged 35 to 49 years who had at least a 25% lifetime risk of breast cancer (19% proven to have a *BRCA* mutation) at 22 centers in the UK.[11] After a median of 3 rounds of screening, 35 cancers (29 invasive) were diagnosed. Sensitivity of MRI was 77%, compared with 40% for mammography, with specificities of 81% and 93%, respectively. MRI was most sensitive and mammography least sensitive for women with *BRCA1* mutations. Forty-five percent of the cancers were 1 cm or less in size, and 14% had spread to axillary lymph nodes. There were two interval cancers.

Warner et al screened 236 women aged 25 to 65 years with a *BRCA* mutation at a single center in Toronto for up to 3 years and detected 22 cancers (16 invasive).[14] Sensitivity of MRI was 77%, compared with 36% for mammography, with 50% of the cancers 1 cm or smaller, and 13% were node positive. There was one interval cancer. Specificity was 95% for MRI and 99.8% for mammography.

Kuhl et al screened 529 women aged 30 years and older with a lifetime breast cancer risk of at least 20% at a single center in Bonn for a mean of 5 years.[10] They detected 43 cancers (34 invasive), with 1 interval cancer. The sensitivity of MRI was 91%, compared with 33% for mammography. The node positive rate was 16%. Specificity of both MRI and mammography was 97%.

The International Breast MRI Consortium screened 390 women aged 25 years and older with more than a 25% lifetime risk of breast cancer at 13 centers (predominantly in the US) on a single occasion.[12] Four cancers were found by MRI, and only one of these by mammography. However, because the patients were not followed after screening, the false-negative rate could not be determined. MRI specificity was 95%, compared with 98% for mammography.

In a study in Italy with 9 participating centers, Sardanelli et al screened 278 women aged 25 years and older; 27% carried a *BRCA* mutation or had a first-degree relative with a *BRCA* mutation.[13] After a median of 1.4 rounds of screening, 18 cancers (14 invasive) were found. MRI sensitivity was 94%, compared with 59% for mammography, 65% for ultrasound, and 50% for clinical breast examination. MRI specificity was 99%.

Overall, studies have found high sensitivity for MRI, ranging from 71% to 100% versus 16% to 40% for mammography in these high-risk populations. Three studies included ultrasound, which had sensitivity similar to mammography. The Canadian, Dutch, and UK studies[9,11,14] reported similar sensitivity (71% to 77%) within CIs for MRI, although the single-center study from Germany10 reported a higher sensitivity, which may reflect the concentration of radiological practice and higher patient volume per radiologist at a single center. There is evidence of a learning curve for radiologists conducting MRI breast screening, with the number of lesions investigated falling with experience.[60] The three multicenter studies reflect the likely initial effectiveness of this modality in a population context, and it is expected that, with training and advances in technology, sensitivity will increase further.

Table 2 provides a summary of these six screening studies.

View this table: TABLE 2 Published Breast MRI Screening Study Results
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Most of the available data are based on screening women at high risk due to family history and/or genetic mutations. More recently, smaller studies have provided information on the potential benefit of MRI screening for women with clinical factors that put them at increased risk. Preliminary data were obtained from one retrospective study, in which Port et al[61] reviewed the screening results of 252 women with biopsy-confirmed LCIS and 126 women with atypical hyperplasia (either ductal or lobular), of whom half were screened with annual mammography and biennial clinical exams and half were also screened with MRI. The women who were screened with MRI were younger and more likely to have a strong family history. MRI screening offered a small advantage to patients with LCIS, but not atypical hyperplasia, and also resulted in increased biopsies: 6 cancers were detected by MRI in 5 women with LCIS (4% of patients undergoing MRI), and none were detected in women with atypical hyperplasia. Biopsies were recommended for 25% of MRI screened patients; 13% of biopsies had a cancer detected. All of the cancers in women screened with MRI were Stage 0 to I, whereas all of the cancers in women who were not screened with MRI were Stage I to II. Cancer was detected on the first MRI in 4 of 5 patients. The sensitivity of MRI was 75%, the specificity was 92%, and the positive predictive value was 13%.

Technological Limitations and Potential Harms Associated with MRI Screening

Although the efficacy of breast MRI has been demonstrated, it does not achieve perfect sensitivity or specificity in women undergoing screening, and as such, the issue of adverse consequences for women who do, but especially those who do not, have breast cancer is important to address. As with mammography and other screening tests, false negatives after MRI screening can be attributed to inherent technological limitations of MRI, patient characteristics, quality assurance failures, and human error; false positives also can be attributed to these factors, as well as heightened medical-legal concerns over the consequence of missed cancers. A patient's desire for definitive findings in the presence of a low-suspicion lesion may also contribute to a higher rate of benign biopsies. The consequences of all these factors include missed cancers, with potentially worse prognosis, as well as anxiety and potential harms associated with interventions for benign lesions.

The specificity of MRI is significantly lower than that of mammography in all studies to date, resulting in more recalls and biopsies. Call-back rates for additional imaging ranged from 8% to 17% in the MRI screening studies, and biopsy rates ranged from 3% to 15%.[9,14] However, several researchers have reported that recall rates decreased in subsequent rounds of screening: prevalence screens had the highest false-positive rates, which subsequently dropped to less than 10%.[9,62,63] Most call backs can be resolved without biopsy. The call-back and biopsy rates of MRI are higher than for mammography in high-risk populations; while the increased sensitivity of MRI leads to a higher call-back rate, it also leads to a higher number of cancers detected. The proportion of biopsies that are

cancerous (positive predictive value) is 20% to 40%.[9, 14] Since false-positive results appear to be common, more data are needed on factors associated with lower specificity rates.

Table 3 compares the likelihood of detection and follow-up tests for women who underwent screening MRI and mammography in two screening studies (Dutch and UK). The study populations differed, with the Dutch study having a wider age group and lower risk category, compared with the UK study.[9,11] This affected both the prevalence of cancer and the pick-up rate by modality in the two studies. These results, drawn from two trials, demonstrate the relatively high recall rate in the high-risk population, as well as the fact that MRI is a relatively new technique. Despite the high number of recalls, because of the high cancer rate, the rate of benign surgical biopsy in the UK study per cancer detected was similar to that experienced in the population-based national breast screening service. Recalls will inevitably lead to additional investigations, many of which will not demonstrate that cancer is present.

View this table: [in this window] [in a new window] TABLE 3 Rates of Detection and Follow-up Tests for Screening MRI Compared with Mammography

Given the high rate of cancer combined with the risk of false-positive scans in a high-risk population undergoing MRI-based screening, the psychological health of these women merits study. In a subgroup of 611 women in the UK study, 89% reported that they definitely intended to return for further screening, and only 1% definitely intended not to return. However, 4% found breast MRI "extremely distressing," and 47% reported still having intrusive thoughts about the examination 6 weeks afterward.[64]

In a sample of 357 women from the Dutch study, psychological distress remained within normal limits throughout screening for the group as a whole. However, elevated breast cancer-specific distress related to screening was found in excessive (at least once per week) breast self-examiners, risk overestimators, and women closely involved in the breast cancer case of a sister. At least 35% of the total sample belonged to one of these subgroups. It was recommended that patients in one of these vulnerable subgroups be approached for additional psychological support.[65]

In a small sample of women from the Toronto study followed over a course of 2 years, there was no evidence of any effect on global anxiety, depression, or breast cancer-related anxiety.[66] In another sample of 57 women, almost 50% had elevated baseline general and or breast cancer-specific anxiety, but in 77% of cases this was attributed by the patients to life events, including relatives with cancer. A nonsignificant increase in general anxiety and breast cancer-related anxiety, compared with baseline, was found in the subset of women recalled for further imaging or biopsies.[67] Follow-up time is still insufficient to determine whether anxiety scores return to baseline once the work up has been completed.

There is a special responsibility to alert patients to this technology, with its potential strengths and harms, and to be encouraging, while allowing for shared decision making. The interplay between risks, benefits, limitations, and harms is complicated by the fact that individual women likely will weigh these differently depending on their age, values, perception of risk, and their understanding of the issues. Steps should be taken to reduce anxiety associated with screening and the waiting time to diagnosis, and conscientious efforts should be made to inform women about the likelihood of both false-negative and false-positive findings. How information is conveyed to the patient greatly influences the patient's response: it is important that providers not convey an undue sense of anxiety about a positive MRI finding. While the high rate of biopsies and further investigations is acceptable in women with a high risk of breast cancer, the number of such investigations in women at lower risk will be much higher than would be appropriate, leading to the need to counsel women in lower risk categories that MRI screening is not advisable and

that the harms are believed to outweigh the benefits. Such advice needs to be based on considerations of family history, genetic mutation status, other risk factors, age, and mammographic breast density.

There are substantial concerns about costs of and limited access to high-quality MRI breast screening services for women with familial risk. In addition, MRI-guided biopsies are not widely available. With many communities not providing MRI screening and with MRI-guided biopsies not widely available, it is recognized that these recommendations may generate concerns in high-risk women who may have limited access to this technology.

The ability of MRI to detect breast cancer (both invasive and in situ disease) is directly related to high-quality imaging, particularly the signal-to-noise ratio, as well as spatial resolution of the MR image. In order to detect early breast cancer (ie, small invasive cancers, as well as DCIS), simultaneous imaging of both breasts with high spatial resolution is favored. High spatial resolution imaging should be performed with a breast coil on a high field magnet with thin slices and high matrix (approximately 1 mm in-plane resolution). These technical parameters are considered to be the minimal requirements to perform an adequate breast MRI study. The ability to perform MRI-guided biopsy is absolutely essential to offering screening MRI, as many cancers (particularly early cancers) will be identified only on MRI. The American College of Radiology (ACR) is currently developing an accreditation process for performing breast MRI, and, in addition to the performance of high spatial resolution images, the ability to perform MRI intervention (ie, needle localization and/or biopsy) will be essential in order to obtain accreditation by this group. Accreditation will be voluntary and not mandatory. This guideline will likely be available in 2007.

There is a learning curve with respect to interpretation for radiologists. Published trial sites that experience a high volume of cases are experienced, but community practice groups have reported call-back rates over 50% in the majority of the studies that are interpreted. Experience and familiarity with patterns of enhancement, normal and possibly abnormal, are thought to decrease recall rates and increase positive biopsy rates. The ACR accreditation process will stipulate a minimum number of exams that must be read for training purposes and a minimum number for ongoing accreditation. Sites performing breast MRI are encouraged to audit their call-back rates, biopsy rates, and positive biopsy rates.

Cost-effectiveness

Only limited data are available on the cost-effectiveness of breast MRI screening. One recent study modeled cost-effectiveness for adding MRI to mammography screening for women of different age groups who carry a *BRCA1* or *BRCA2* mutation.[68] The authors concluded that the cost per quality-adjusted life year (QALY) saved for annual MRI plus film mammography, compared with annual film mammography alone, varied by age and was more favorable in carriers of a mutation in *BRCA1* than *BRCA2* because *BRCA1* mutations confer higher cancer risk, and higher risk of more aggressive cancers, than *BRCA2* mutations.[31] Estimated cost per QALY for women aged 35 to 54 years was $55,420 for women with a *BRCA1* mutation and $130,695 for women with a *BRCA2* mutation. Cost-effectiveness was increased when the sensitivity of mammography was lower, such as in women with very dense breasts on mammography: estimated costs per QALY were $41,183 for women with a *BRCA1* mutation and $98,454 for women with a *BRCA2* mutation with dense breast tissue. The most important determinants of cost-effectiveness were breast cancer risk, mammography sensitivity, MRI cost, and quality of life gains from MRI.

An evaluation of the cost-effectiveness of the UK study[69] has determined that the incremental cost per cancer detected for women at approximately 50% risk of carrying a *BRCA* gene mutation was $50,911 for MRI combined with mammography over mammography alone. For known mutation carriers, the incremental cost per cancer detected decreased to $27,544 for MRI combined with mammography, compared with mammography alone. Analysis supporting the introduction of targeted MRI screening in the UK for high-risk women70 identified the incremental cost of combined screening per QALY in 40- to 49-year-old women as $14,005 for a *BRCA1* carrier with a 31% 10-year riskthe group in which MRI screening is seen to be most effective; $53,320 for women with a 12% 10-year risk; and $96,379 for women with a 6% 10-year risk. For the 30- to 39-year-old age range, the incremental costs per QALY are $24,275 for a *BRCA1* carrier with an 11% 10-year risk and $70,054 for a women

with a 5% 10-year risk. Based on these estimates, which are based on costs within the UK National Health Service, MRI screening will be offered to women at familial risk aged 30 to 39 years at a 10-year risk greater than 8%, and to women at familial risk aged 40 to 49 years at a 10-year risk greater than 20%, or greater than 12% when mammography has shown a dense breast pattern.

Evidence Supporting Benefit of MRI Screening Among Women in Different Risk Categories

The guideline recommendations were based on consideration of (1) estimates of level of risk for women in various categories and (2) the extent to which risk groups have been included in MRI studies, or to which subgroup-specific evidence is available. Because of the high false-positive rate of MRI screening, and because women at higher risk of breast cancer are much more likely to benefit than women at lower risk, screening should be recommended only to women who have a high prior probability of breast cancer. There is growing evidence that breast cancer in women with specific mutations may have biological and histological features that differ from sporadic cancers. This may result in observed variations in the sensitivity of MRI relative to mammography in detecting cancer in women with a *BRCA* mutation and those at high familial risk, but without mutations in these genes.[11]

Women at Increased Risk Based on Family History

The threshold for defining a woman as having significantly elevated risk of breast cancer is based on expert opinion. Any woman with a *BRCA1* or *BRCA2* mutation should be considered at high risk. The panel has not restricted its recommendations only to women with *BRCA* mutations because *BRCA* testing is not always available or informative, and other risk indicators identify additional subsets of women with increased breast cancer risk. If mutation testing is not available, has been done and is noninformative, or if a woman chooses not to undergo testing, pedigree characteristics suggesting high risk may be considered. Very careful family history analysis is required, using tools such as BRCAPRO.[18,26] Risk assessment is likely to offer the greatest potential benefit for women under the age of 40 years. Table 4 provides examples of women with a family history indicative of moderate and high risk. The online supplemental material provides guidance for accessing and using risk assessment models.

View this table: TABLE 4 Breast Cancer Risks for Hypothetical Patients, Based on 3 Risk Models
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Women at Increased Risk Based on Clinical Factors

Additional factors that increase the risk of breast cancer, and thus may warrant earlier or more frequent screening, include previous treatment with chest irradiation (eg, for Hodgkin disease), a personal history of LCIS or ADH, mammographically dense breasts, and a personal history of breast cancer, as discussed above. There are little data to assess the benefit of MRI screening in women with these risk factors. Women at increased risk or who are concerned about their risk may find it helpful to have their provider clarify the bases for MRI screening recommendations, as well as areas of uncertainty. For some women, mammography may be as effective as for women at average risk, and MRI screening may have little added benefit. In contrast, mammography is less effective in women with very dense breasts, and MRI screening may offer added benefit.

Women who have received radiation treatment to the chest, such as for Hodgkin disease, compose a well-defined group that is at high risk. Although evidence of the efficacy of MRI screening in this group is lacking, it is expected that MRI screening might offer similar benefit as for women with a strong family history, particularly at younger ages and within 30 years of treatment. Because of the high risk of secondary breast cancer in this group, MRI screening is recommended based on expert consensus opinion.

While lifetime risk of breast cancer for women diagnosed with LCIS may exceed 20%, the risk of invasive breast cancer is continuous and only moderate for risk in the 12 years following local excision.[46] Only one MRI screening

study has included a select group of women with LCIS,[61] which showed a small benefit over mammography alone in detecting cancer. This benefit was not seen in patients with atypical hyperplasia. MRI use should be decided on a case-by-case basis, based on factors such as age, family history, characteristics of the biopsy sample, breast density, and patient preference.

Although there have been several trials reported looking at the accuracy and positive predictive value of MRI and mammography in women with high breast density, all of these trials have been conducted in women with known or highly-suspected malignancies within the breast.[71-74] To this point, there has been no Phase III randomized trial reported that has shown a reduction in either mortality or in the size of diagnosed breast cancer when comparing breast MRI with mammography in women with high mammographic density.

Scant data are available for MRI screening of women with a personal history of breast cancer. In one study, MRI detected more cancers in women who had both a personal history and a family history, compared with women at high risk based on family history alone.[75] While women with a previous diagnosis of breast cancer are at increased risk of a second diagnosis, the ACS panel concluded that the estimated absolute lifetime risk of 10% does not justify a recommendation for MRI screening at the present time.

Limitations of Evidence from MRI Studies and Research Needs

Assiduous attempts were made to base recommendations on solid evidence. However, outcome data from screening MRI studies are not sufficient to form a solid basis for many of the recommendations. It was therefore necessary to rely on available inferential evidence and expert opinion to provide the guidance needed for patients and their health care providers.

Although the literature shows very good evidence for greater sensitivity of MRI than mammography and good evidence for a stage shift toward earlier, more favorable tumor stages by MRI in defined groups of women at increased risk, there are still no data on recurrence or survival rates, and therefore, lead-time bias is still a concern. Further, a large randomized, mortality endpoint study is unlikely to take place, and it will be necessary in the foreseeable future to rely on evidence of stage of disease and types of cancers. In the absence of randomized trials, recurrence and survival data will come from observational study designs.

The age at which screening should be initiated for women at high risk is not well established. The argument for early screening is based on the cumulative risk of breast cancer in women with *BRCA1* mutations and a strong family history of early breast cancer, which is estimated to be 3% by age 30 years and 19% by age 40 years.[76] Population-based data also indicate that risk for early breast cancer is increased by a family history of early breast cancer.[16] Based on these observations, some experts have suggested that breast cancer screening begin 5 to 10 years before the earliest previous breast cancer in the family. In 1997, an expert panel suggested that screening be initiated at some time between the ages of 25 and 35 years for women with a *BRCA1* or *BRCA2* mutation.[77] Because these recommendations were based on limited observational data, the decision regarding when to initiate screening should be based on shared decision making, taking into consideration individual circumstances and preferences. No data are available related to the effectiveness of screening women beyond age 69 years with MRI and mammography versus mammography alone; most of the current data are based on screening in younger women, and thus, similar investigations are needed in older age cohorts. For most women at high risk, screening with MRI and mammography should begin at age 30 years and continue for as long as a woman is in good health.[1]

Most of the available data are based on annual MRI screening; there is a lack of evidence regarding shorter or longer screening intervals. Further, while good data are available for the first screening exam (ie, the "prevalent screen"), considerably less data are available from subsequent screening exams (ie, "incidence screens"), and the available data include relatively short follow-up times. Most studies of annual MRI have shown few interval cancers, certainly fewer than with mammography. Given the probably shorter duration of the detectable preclinical phase, or sojourn time, in women with *BRCA* mutations, MRI has demonstrated superiority to mammography in this

regard. Therefore, to the best of our knowledge, MRI should be performed annually. However, in view of data suggesting that tumor doubling time in women with an inherited risk decreases with age,78 it is conceivable that older women can safely be screened less frequently than younger women. The available evidence is limited, and additional research regarding optimal screening interval by age and risk status is needed.

Some experts recommend staggering MRI screening and mammography screening every 6 months. The potential advantage of this approach is that it may reduce the rate of interval cancers. Other experts recommend MRI and mammography at the same time or within a short time period. This approach allows for the results of both screening tests to be interpreted together and reported to the patient at the same time. All of the clinical trials screened participants with both MRI and mammography at the same time. There is no evidence to support one approach over the other. For the majority of women at high risk, it is critical that MRI screening be provided in addition to, not instead of, mammography, as the sensitivity and cancer yield of MRI and mammography combined is greater than for MRI alone. However, where there is a concern about raised radiation sensitivity, it may be advisable to employ MRI alone despite the overall lower sensitivity.

In order to pursue answers to some of the unresolved questions related to the use of MRI and mammography to screen women at increased risk, it is important to develop creative strategies related to data gathering and study design. Multicenter studies can result in greater efficiency in accumulating sufficiently large enough data sets in this subgroup of women. Conventional study designs with randomization may prove difficult given the potential advantage of adding MRI to mammography in higher-risk groups, and thus, design strategies that utilize surrogate markers and historic controls may prove both more practical and feasible. To move forward, we encourage the development of a simple, common data collection protocol to capture information from the growing number of centers that offer MRI and formal systems to collect outcome data. Because many insurers presently cover MRI screening for high-risk women, it may be economical to do prospective surveillance studies since screening costs are covered by third parties. A common surveillance protocol could permit pooling of data, much like presently is done within the framework of the National Cancer Institute's Breast Cancer Surveillance Consortium, a collaborative network of seven mammography registries in the United States with linkages to tumor and or pathology registries that was organized to study the delivery and quality of breast cancer screening and related patient outcomes in the United States.[79] We also encourage seeking opportunities for broad international research collaboration on study questions of common interest.

Several further clinical trials of screening women at increased risk of breast cancer are underway, including an international study of MRI and ultrasound in conjunction with the International Breast MRI Consortium and Cancer Genetics Network, and the American College of Radiology Imaging Network (ACRIN) 666 screening trial of mammography compared with ultrasound. An amendment to the ACRIN trial, 6666, will screen patients with one round of MRI.

CONCLUSION

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Often no available screening modality is uniquely ideal. For breast MRI, there is an increasing body of observational data showing that screening can identify cancer in patients of specific risk groups, ie, high-risk patients facing a lifetime risk of ~20–25% or greater related to family history as estimated by one or more of the different risk models. We have specified a range of risk because estimates from the risk models vary and because each of the risk models is imperfect. Furthermore, these models likely will continue to be refined over time; therefore, these risk estimates for different family history profiles are likely to change. Thus, when estimating patient risk it is important to always be certain that the most current model is being used. In addition to family

history, clinical factors as described earlier may be a relevant factor in individualized decisions about MRI screening when family history alone does not predict a risk of approximately 20–25%.

Several studies have demonstrated the ability of MRI screening to detect cancer with early-stage tumors that are associated with better outcomes. While survival or mortality data are not available, MRI has higher sensitivity and finds smaller tumors, compared with mammography, and the types of cancers found with MRI are the types that contribute to reduced mortality. It is reasonable to extrapolate that detection of noninvasive (DCIS) and small invasive cancers will lead to mortality benefit.

The guideline recommendations for MRI screening as an adjunct to mammography for women at increased risk of breast cancer take into account the available evidence on efficacy and effectiveness of MRI screening, estimates of level of risk for women in various categories based on both family history and clinical factors, and expert consensus opinion where evidence for certain risk groups is lacking. All of these groups of women should be offered clinical trials of MRI screening, if available. Women should be informed about the benefits, limitations, and potential harms of MRI screening, including the likelihood of false-positive findings. Recommendations are conditional on an acceptable level of quality of MRI screening, which should be performed by experienced providers in facilities that provide MRI-guided biopsy for the follow up of any suspicious results.

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Members: Christy A. Russell, MD (Chair); Associate Professor of Medicine, Keck School of Medicine, University of Southern California; and Co-Director of USC/Norris Breast Center, Los Angeles, CA; **Barbara Andreozzi**; Prevention Chair, Montana Comprehensive Cancer Control Coalition; and Community Development Specialist, Montana State University Extension Service, Anaconda, MT; **Gena R. Carter, MD**; Radiologist, InMed Diagnostic Women's Center, Norwell, MA; **Lynn Erdman, RN, MS**; Senior Vice President, North Carolina and South Carolina, American Cancer Society, South Atlantic Division, Charlotte, NC; **W. P. Evans, III, MD**; Professor of Radiology; and Director of the University of Texas Southwestern Center for Breast Care, Dallas, TX; **Herschel W. Lawson, MD**; Senior Medical Advisor, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention, Atlanta, GA; **Maggie Rinehart-Ayers, PhD, PT**; Associate Professor and Director of Clinical Education, Thomas Jefferson University, Jefferson College of Health Professions, Philadelphia, PA; **Carolyn D. Runowicz, MD**; Professor of Obstetrics and Gynecology; NEU Chair in Experimental Oncology; and Director of the Neag Comprehensive Cancer Center, University of Connecticut Health Center, Farmington, CT; **Debbie Saslow, PhD**; Director, Breast and Gynecologic Cancer, Cancer Control Science Department, American Cancer Society, Atlanta, GA; **Stephen Sener, MD**; Vice Chairman, Department of Surgery, Evanston Northwestern Health Care, Evanston, IL; and Professor of Surgery, Northwestern University Feinberg School of Medicine, Chicago, IL; **Robert A. Smith, PhD**; Director, Cancer Screening, Cancer Control Science Department, American Cancer Society, Atlanta, GA; **William C. Wood, MD**; Professor; and Chairman, Department of Surgery, Emory University School of Medicine, Atlanta, GA

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Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Comment – 4: HOPE, A Women's Cancer Center

Asheville PH
July 13 2007

Hope
A Women's Cancer Center

SHCC Public Hearing Presentation Comments
Adjusted Need Determination – 2008 State Medical Facilities Plan
Dedicated Breast MRI Scanner in HSA I
July 13, 2007

Good afternoon, my name is Mariann Smith. I am the Administrator at Hope – A Women's Cancer Center in Asheville. I am here today to speak on behalf of our petition for an adjusted need determination for one dedicated breast MRI scanner in Buncombe County to serve residents in HSA I.

Approval of this petition will enable any eligible applicant the opportunity to submit competitive Certificate of Need applications proposing the best plan for addition of a dedicated breast MRI scanner in Buncombe County.

Breast cancer is the most common cancer among women. The chance of developing invasive breast cancer at some time in a woman's life is about 1 in 7. For breast cancer, early detection saves lives. For example, almost 98 percent of women who are diagnosed with breast cancer in the earliest stage survive the disease, whereas only 26 percent survive if the disease is diagnosed in the most advanced stage. The opportunity for disease control and for reducing the number of cancer deaths rests with prevention and early detection so that treatment of the disease can be effective. This is the foundation of our petition for a dedicated breast MRI scanner in Buncombe County.

Hope is aware that the 2006 State Medical Facilities Plan included an adjusted need determination for a dedicated and specialized breast MRI scanner. This adjusted need determination was the result of a petition submitted by Novant Health. This petition was based on American Cancer Guidelines that were released in 2003 stating women might benefit from additional screening strategies beyond those offered to women at average risk. However, new evidence on breast MRI screening has become available since the American

Cancer Society last issued guidelines in 2003. A guideline panel has reviewed this evidence and developed new recommendations for women at different levels of risk.

According to the American Cancer Society, women with a genetic predisposition to breast cancer, and/or those with a family history of the disease, should undergo annual MRI screening along with routine mammograms.
Specific guidelines were released in March of 2007 identifying the women who should have a breast MRI scan. These guidelines include:

- Those who are BRCA mutation carriers;
- Women with first-degree relatives who are BRCA mutation carriers;
- Women with a 20% to 25% lifetime risk of breast cancer based on family history;
- Women who had radiation treatment to the chest between the ages of 10 and 30; and
- Women with specific genetic syndromes.

The guideline states that, for high-risk women, screening with MRI and mammography should begin at age 30. These new guidelines demonstrate that a much larger population can benefit from breast MRI screening compared to the 2003 guidelines. Based on the 2007 American Cancer Society guidelines, geography and demographic data, a dedicated breast MRI scanner is of great need for residents of Buncombe County and HSA I.

I previously mentioned that one guideline for identifying women who should have a breast MRI scan are those who are BRCA mutation carriers. The prevalence of BRCA mutations is estimated to be between 1/500 and 1/100 in the general population. This equates to approximately 445 Buncombe County residents and over 2,700 people in HSA I who could benefit from a breast MRI scanner.

The guidelines also state that women with a 20% to 25% lifetime risk of breast cancer based on family history should have a breast MRI. According to the American Cancer Society, 2% of women have a family history suggestive of breast cancer inheritance. While 2% may sound nominal, this equates to as many as 2,000 women in Buncombe County and 13,000 women in HSA I.

I've only described two of the guidelines for selecting women who will benefit from a breast MRI scanner. The guidelines outline five specific populations of women for which evidence proves breast MRI can detect breast cancer. Our petition, which will be submitted in August, provides greater detail regarding these guidelines.

Based on the 2007 SMFP, residents currently have access to dedicated breast MRI services in HSA II. Residents in HSA III will have soon have access to dedicated breast MRI services pursuant to the 2006 SMFP adjusted need determination. Residents of HSA I do not have access to dedicated breast MRI services. It is well known that it is very difficult for residents of western North Carolina to travel long distances for healthcare services. Furthermore, the 2007 American Cancer Society guidelines identify a greater population of women who can benefit from breast MRI. A dedicated breast MRI scanner is needed in Buncombe County to serve HSA I residents.

Hope is a skilled women's cancer center experienced in treating women with cancer such as breast, ovarian, and cervical cancer. We have provided women's healthcare services to patients of western North Carolina for over 14 years.

Hope physicians are primary investigators for the Gynecologic Oncology Group in western North Carolina. The GOG is the primary study group for women's cancers in the United States. Hope is also a cooperative group with the American College of Surgeons - Oncology Group and participates in breast cancer trials. In addition Hope participates in other clinical trials through Cancer Trials Support Unit which is a clearinghouse to facilitate enrollment in clinical trials that are sponsored by other cooperative groups. The National Cancer Institute (NCI) works with the GOG, other cooperative groups and most of the major cancer centers to develop new treatments or fine-tuning existing ones. These changes usually lead to improving the standard of care.

Hope seeks to improve the standard of care in western North Carolina via an adjusted need determination for a breast MRI scanner.

We feel there is a clear need for a dedicated breast MRI scanner in Buncombe County. We hope you will support us in this effort by approving this petition for an adjusted need determination. Thank you for providing me with the opportunity to discuss this important issue.

Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

MRI Comments – Upright MRI

NCHA
PO Box 4449
Cary, NC 27519 - 4449

919 / 677-2400
919 / 677-4200 fax
www.ncha.org

August 3, 2007

Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins and members of the State Health Coordinating Council:

The Proposed 2008 State Medical Facilities Plan (SMFP) includes an adjusted need determination for four demonstration projects of one fixed multi-position MRI scanner each. For the following reasons, NCHA recommends that the Council re-establish this need determination at the level of two scanners that was recommended by the Technology & Equipment Committee.

- To date no CON applications for this technology have been submitted, nor have any requests to replace existing MRI equipment with this technology been filed. Given the apparent limited interest in the technology, we recommend that the SHCC move cautiously by establishing fewer need determinations, as it has with previous specialized MRI scanners. Establishing two demonstration projects will enable a careful assessment of the clinical benefits and the utilization and payer mix trends of the technology.

- The demonstration project, as described in the Proposed 2008 SMFP, places the four scanners into the inventory after the first year of operation. If patient volumes for the upright scanner prove to be low, a corresponding drop in the average scan volume per machine could inhibit the need for additional full-service MRIs in the service area. Establishing two demonstration projects improves the chance of success for each of the upright scanners while reducing the chance of a negative impact to the MRI service areas where they are developed.

- As a 0.6T MRI system, the scanners field strength is lower than that of most equipment in the state. Many of the lower-field strength MRI systems are being phased out by MRI service providers in North Carolina.

- The recommendation of two scanners by the Technology & Equipment Committee already exceeds the number requested by Governor Easley in the 2007 SMFP and is comparable to the number approved prior demonstration projects.

Thank you for the opportunity to comment on the Proposed 2008 State Medical Facilities Plan and please feel free to contact me if you have questions

Sincerely,

Mike Vicario
Vice-President of Regulatory Affairs

Raleigh PH
8-1-07
Upright MRI

NICK GALIFIANAKIS & ASSOCIATES
ATTORNEYS AT LAW
P. O. BOX 1611
DURHAM, NORTH CAROLINA 27702-1611

NICK GALIFIANAKIS
ATTORNEY AT LAW
CERTIFIED MEDIATOR
*Also licensed in District of Columbia

301 WEST MAIN STREET, SUITE 200
DURHAM, NC 27701
TELEPHONE (919) 682-5403
FAX (919) 688-0608
E-mail nglaw@mindspring.com

August 1, 2007

Good afternoon. My name is Ruben Fernandez, and I am here on behalf of myself, and of Senator Galifianakis to comment on the allowance of four Certificates of Need for Upright MRI machines.

First of all, I would like to than the Governor, Mike Easley, for recognizing the need for these machines. Second, I would like to thank the Committee for recommending that four of them be placed in this State. The way that our Certificate of Need process works relies on the hard work of a lot of people, and it is only through them that the State of North Carolina can continue to have state of the art medical facilities.

The upright MRI has been recognized by the United States Military, and by Congress as an important diagnostic tool, and for its invention, Dr Damadian was awarded the Congressional Inventor of the Year award this year.

For those of you here who are not on the Technology committee, these upright MRI machines differ from the MRI machines that we currently have in North Carolina in that they can take images of patients in all positions, not just lying down, but standing up, sitting, standing on their heads, whatever. The great benefit of this is that they can take images of the human body while it is under the stress of having weight put on its joints, spine, etc...

While these machines are not a replacement for the traditional MRI machines we already have in place, they do provide a specialized type of scans for doctors, like orthopedic surgeons, who need to work on a patient's spine or joints, or other parts of the body that move and shift under load. It is because these machines are specialized that we need these Certificates issued to place them. A specialized MRI will always serve a smaller percentage of the population than a more general purpose MRI, combine that with the fact that these MRI machines are not as profitable to operate, and it is easy to see why they have trouble competing for a CON with the traditional MRI machines that keep getting put in.

Right now, if my doctor wants to look at an MRI of my spine while I'm standing up, I need to fly to another state to get it done. I don't think that's the kind of medical service we want in this state.

There are several Orthopedic centers in North Carolina who want access to these machines. Some of them have already tries to put them in, they just need a Certificate like the one proposed to be issued so they can put them in.

With that, I thank you for your time.

Carolinas HealthCare System

James T. S. Hunter
Chairman

Michael C. Lancaster, FACHE
President & CEO

August 2, 2007

Dan A. Myers, M.D.
Chairman, North Carolina State Health Coordinating Council
c/o Medical Facilities Planning Section
Division of Health Service Regulation
701 Barbour Drive
Raleigh, North Carolina 27603-2008

Dear Dr. Myers:

I am writing in regard to the demonstration project for four fixed multi-position MRI scanners contained on page 139 of the Proposed 2008 State Medical Facilities Plan (SMFP). I am recommending this section of the proposed SMFP be changed to include only two multi-position scanners (one for each side of the state). The rationale for this recommendation is summarized below:

- ☐ After careful review of the key issues and position outlined by Axiom Imaging in its petition to include one scanner in each of the state's HSAs, Medical Facilities Planning staff recommended to the Technology and Equipment Committee that one such scanner be placed in the 2008 SMFP. After its consideration, the Technology and Equipment Committee recommended two scanners statewide. My recommendation is congruent with the direction provided by the Technology and Equipment Committee.

- ☐ On May 30, the SHCC voted to increase the Technology and Equipment Committee recommendation from two scanners to four. During this SHCC meeting, I do not believe the members of the SHCC had full and complete knowledge of the facts surrounding this technology as follows:

    - Based on our research, the manufacturer of the demonstration scanner is Fonar. To date, it appears Fonar has sold approximately 120 scanners worldwide over the past eight years. With the proposed demonstration project as is, North Carolina is proposing to add three percent to the worldwide market inventory

for this particular scanner. These data points provide insight into the magnitude of placing four scanners in the SMFP in a single year.

- The proposed scanner is a 0.6T MRI system. Image quality for this particular scanner is noticeably inferior to 1.5T and 3.0T systems. The current replacement market for MRI in North Carolina is showing a high preference for advanced versions of 1.5T MRI systems and a growing installation of 3.0T MRI systems. 0.6T scanners and similar lower field strength MRI systems have been or are being phased out by several owners of this equipment in the state.

- Four multi-position scanners represent a 36 percent increase in the total number of MRI scanners in the 2008 SMFP as the proposed SMFP already shows the need for 11 fixed scanners statewide. On a comparative basis, adding four additional scanners in a demonstration project appears significantly aggressive as four of 15 additional scanners are arbitrary in nature versus the 11 scanners that are based on the need methodology formula. *It is noted there is no prohibition against proposing an upright MRI scanner in response to the 11 scanners already cited as needed in the plan.*

- It is also noted that the multi-position scanner proposed in the demonstration project has been available for sale in North Carolina for the past six years. During this period, a total of 77 additional fixed MRI scanners have been approved under the state health planning process (2002-2006 SMFPs). During this period of time, no physician practice, imaging center or hospital has purchased the multi-position scanner proposed in this demonstration project.

❒ Including two scanners in this demonstration project will allow the state to evaluate the benefits and the utilization and payer mix trends of the project before additional scanners of this type are placed in the SMFP. This approach is more consistent with how the state has handled the past three MRI demonstration projects, including breast, extremity and pediatric, whereby only one scanner was available under the initial demonstration.

We appreciate the opportunity to offer these comments as you, your staff and the SHCC work to finalize the 2008 State Medical Facilities Plan over the next several months. If you should have any questions regarding the above information and comments, please give me a call.

Sincerely,

F. Del Murphy, Jr.
Vice President

SHCC Public Hearing Presentation Comments for Support of Adjusted Need Determination for 4 Demonstration Projects for Multi-position MRI Scanners

Presented by Charles Wilson, Chief Executive Officer
Triangle Orthopaedic Associates
Durham, North Carolina

July 24, 2007

Good afternoon, my name is Charles Wilson and I am the Chief Executive Officer for Triangle Orthopaedic Associates. I am here today to speak in support of the adjusted need determination published in the Proposed 2008 State Medical Facilities Plan, for four demonstration projects for multi-position MRI scanners to be located in western and eastern North Carolina.

As has been discussed and debated by members of the SHCC's Technology and Equipment Committee in meetings this past winter and spring, recent studies have concluded that imaging of the spine in the erect standing and seated positions adds significantly to the diagnostic ability of MRI. We note as significant that Governor Michael Easley, in approving the 2007 State Medical Facilities Plan, specifically requested the SHCC to study the need for an upright MRI scanner, and consider including such a need in the 2008 SMFP.

The upright, multi-position MRI scanner is a fast scanning, high-resolution whole body imaging system operating at 0.6 Tesla. Also known as the "Stand-Up MRI", it is the only whole-body scanner with the ability to scan patients in a multitude of positions, including in weight-bearing positions and in the positions of symptoms or pain. The intent of allowing CONs for multi-position MRI scanners is to benefit patients for whom conventional MRI scans have proven uninformative as to their ailments, as is often the case for those who experience back and joint pain when standing, sitting or moving, as opposed to simply lying down. The diagnostic information yielded by the upright MRI scanner offers superior ability to obtain accurate diagnoses when compared to recumbent imaged obtained by conventional MRI scanners. Our orthopedic physicians, who deal with the spine and its injuries, envision real benefits to patients from this technology, and are anxious to see this imaging technology in North Carolina. A multi-position MRI scanner gives a more accurate diagnosis of the spine and joints in the actual positions that cause pain. This allows for a more accurate diagnosis of the problem, and enables a higher success rate for orthopedic surgery.

In addition, claustrophobia is a major deterrent to having an MRI scan for a significant portion of the population. Barring sedation, many patients scheduled for MRI scans in conventional scanners cannot complete the

procedure due to claustrophobia.[1] A multi-position MRI scanner removes barriers that discourage or prevent claustrophobic individuals from having needed MRI scans, by providing the scans in an open environment, as opposed to being scanned in a tight cylinder, as is the case in a conventional MRI scanner.

As the SHCC already knows, the multi-position MRI scanner has gained acceptance throughout the United States, including in all the states surrounding North Carolina. Virginia has three, and Georgia, Tennessee and South Carolina each have one such scanner.

Given competitive realties of fixed MRI reviews, it is extremely difficult for specialized MRI scanners (like an upright MRI scanner or an extremity MRI scanner) to serve as many patients as a general use scanner. Therefore, in a competitive MRI review, a specialized MRI scanner can be considered by the Agency to be a less effective alternative compared to a general use MRI scanner. Inclusion of this adjusted need determination in the Final 2008 SMFP will enable North Carolina residents to have access to equipment that is demonstrated in other states to have significantly better ability to visualize pathology compared to recumbent MRI imaging. Failure to allow the use of this technology in North Carolina may increase long-term health costs, because existing equipment is more likely to mask pathology

[1] Journal of European Radiology, Vol 3, Issue 4, August 1993

in recumbent imaging (especially spinal images). North Carolina residents have a high frequency of back surgeries. Unfortunately, there is a relatively large number of failed back surgeries in our State. As I stated previously, our physicians believe that upright imaging is needed to best obtain the correct diagnosis. The resulting improved diagnostic imaging will lead to better surgical and non-surgical care of our patients.

TOA features a clinical research program dedicated to the advancement of orthopaedic and musculoskeletal medical care through clinical research and education. Our research is directed toward studying new medications or devices which are intended to improve the quality of or the availability of a treatment for a given disease or symptom. The objectives of clinical outcomes data and information are intended to support, or oppose, new methods of treatment, and to determine what new technology provides the best treatment options for patients (for example, upright MRI scanners).

As already determined by the SHCC when it included the adjusted need determination in the proposed 2008 SMFP, there is clearly a need for multi-position MRI scanners in North Carolina. Furthermore, TOA, along with other healthcare providers, already have the resources in place to make excellent use of such upright scanners. We hope the State Health Coordinating Council will help our North Carolina patients by going

ahead with the proposed plan to allow four upright MRI Scanners. Thank you for providing me with the opportunity to discuss this important issue.

August 3, 2007

Mr. Robert J. Fitzgerald, Director
Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Mr. Fitzgerald:

I am respectfully submitting our comments with regard to the demonstration project for four fixed multi-position MRI scanners in the Proposed 2008 State Medical Facilities Plan (SMFP). We appreciate the opportunity to offer these comments as you finalize the 2008 State Medical Facilities Plan over the next several months.

1. Demonstration CON's in North Carolina have historically been limited to one device; authorizing two is more than customary. It is felt that four simultaneous CON's would support a separate regulatory class of MR, not a demonstration project. There is a lack of support for multiple projects based the available market and clinical evidence. Our opinion rests that no demonstration project is needed, but if the state wishes to proceed, the study project should limited to one application in 2008, and a second in 2009. This would give prospective demonstration project applicants the opportunity to compete for the first unit; then refine their applications for the second if desired. This approach would foster better crafted proposals, potentially adding to the value of the project data.

2. The argument that this is a vital technology which North Carolina patients need to access is unproven. The Axiom petition offers an emotional appeal which sounds good, but lacks scientific evidence. There is no literature to support actual improved patient outcomes over current evaluation and treatment techniques. What supporting literature is available can be characterized as anecdotal. Evidence based medicine is now the review standard. Several rigorous medical policy review documents are available, all of which conclude that available evidence is poor.

3. The Axiom petition cites literature generated by individuals associated with the only qualified vendor, Fonar. The cases cited would all be identified by existing evaluation processes. The unspoken implication is that more patients can be identified as surgical candidates, and helped by that surgery, and that these patients would otherwise go on needlessly suffering. No evidence is for the reducing the need for surgery is offered as benefit of using the technology. No actual cost savings are claimed or

documented. Using the logic offered in the petition, and then applying known surgical outcome statistics in the same manner as the petitioners use to justify their application, would indicate the potential improvement in patient outcomes is well below 1%, if that.

4. We feel it is appropriate that Demonstration Upright MRI be excluded from the regular MR inventory in the year it is installed, but become a regular part of the inventory for it's location in subsequent years.

5. Upright MRI should be regulated as a standard MRI system and be capable of competing in the market place on its on merits. There should be no special regulatory categories or statuses created.

6. The Demonstration unit cannot be replaced with another MRI unit for a minimum of 5 years. These units have to offer equal and unprejudicial access to all spinal surgeons. As a practical matter, a unit under the control of one physician group or hospital system will not readily be utilized or supported by competing physician groups or hospital systems. In addition, Medicare anti-kickback and Federal "Stark" rules should govern all referrals to the demonstration systems, regardless of payer status, public or private. Violations of this could result in revocation of the project CON.

7. There are ample opportunities for either new applicants or an existing site to replace an existing unit with an Upright MRI system. To date, no conversions have been proposed or have occurred. However, regardless of what form the proposed demonstration project takes, existing operators or future applicants for CON's can elect to adopt or propose upright MR systems at any time under the existing regulations. There is no substantial barrier to the adoption of this technology other than its own intrinsic qualities.

8. The current replacement market for MR in North Carolina is showing a high preference for advanced version of 1.5T MR systems, along with a growing number of installed 3.0T systems. 0.6T and similar lower field strength systems have been, or are being phased out by current owners of this equipment in North Carolina.

9. There are 120 Fonar systems installed worldwide after more than 8 years of purchase availability. There are no current Fonar installations in North Carolina. This project proposes to add three percent to the world installed base and most likely more than 20% of FY 2007 sales.

10. The Fonar 0.6T MR system enjoys all of the advantages and limitations of a lower strength MR system. Image quality is noticeably inferior to 1.5T and 3.0T systems. The image plane thicknesses used are usually greater than at 1.5T in order to reduce image noise and improve image appearance. This creates small lesion resolution issues, particularly in the

cervical and thoracic spines. Symptomatic small disc herniations can be missed, along with small spinal cord lesions.

11. Low field MRI systems examinations can last as much as 3 times as long as high field systems. This results in an increase in the likelihood of patient motion, thereby adding to the inaccuracies of a low field system.

12. Upright MRI may offer limited value in flexion-extension MRI, which presents a challenge in typical 1.5T and 3.0T systems.

13. Some operators accept lower image quality images to reduce examination times and increase patient throughput.

14. Historical demonstration projects focused on Breast, Orthopedics, and Peds have been approved on a singular basis and have limited the approved applications appropriately. Given that the only compelling rationale offered by the proponents of this technology support this demonstration project has been for spinal imaging, each demonstration project MRI should be limited to only performing spinal imaging during this project duration. This should not cause a community hardship since there is presently no evidence to indicate any significant access problems for MRI services in the HAS. Limiting imaging on this demonstration as well would maximize the date value of the Upright MR Demonstration Project. Such a qualification is both desirable and appropriate given the nature of the project.

15. An alternative spinal axial loading device that can be used in current installed conventional MR systems in the state exists and can be readily obtained and employed if current or future operators so desire. The arguments that upright MRI systems the only ways to evaluate the lumbar spine under axial loading conditions are not entirely correct. This spinal axial loading device, titled the Portal Gravity System, Portal Medical, Logan Utah, is available for purchase. There is a paper validating that this device effectively simulates upright imaging results. Like upright MRI, this approach lacks compelling outcomes evidence at this time.

16. There is no evidence to support the value in imaging post operative spinal patients in an upright position.

17. An application for a unique CPT code for upright MRI was received by the CPT Editorial Panel and denied due to a lack of compelling evidence.

18. The sales literature cites that placing a patient in a position that recreates their pain can assist in the localization of abnormalities that may not be seen in a recumbent state. The patient pain stimulus would most likely be a reason for motion during the long exam times exhibited on low field systems.

19. Orthopedic work will be marginal similar to open MRI technology. Lower field strength limits accuracy, image quality. Likewise, the ability to offer upright imaging in orthopedics has limited utility and greatly increases the probability of patient motion.

20. Extensive research along with current clinical Breast Cancer imaging supports a temporal approach unattainable with low field systems.

21. Intra and Extra-cranial blood flow dynamics do change in an upright posture. Again, this may offer limited utility as an adjunct imaging procedure. More research is need in this area.

22. Facility must operate a minimum of 66 hours per week.

23. There should be full disclosure of the MR system and site ownership including names of all physician investors and their relatives. Also, disclosure of any consultant payments, lease arrangements, and assigned billing arrangements.

24. Annual reports should be made to the CON and Medical Facilities planning Section reporting:

    - The number of exams performed in an upright position.
    - Total number of exams.
    - The CPT code data for all performed exams.
    - Patient payer mix of insured, under-insured, and un-insured.
    - Referring doctor and patient origin data.
    - Itemized billing with specifically identified technical and professional charges and who provided those services as actually submitted for payment.
    - Facility revenue and operating expenses.

Sincerely,

CHARLOTTE RADIOLOGY, P.A.

Mark D. Jensen
Chief Operating Officer

MDJ:js

Rec'd @ July 30, 2007 Public Hearing in Wilmington

July 30, 2007

North Carolina State Health Coordinating Council
Proposed 2008 State Medical Facilities Plan
Coastal AHEC, Wilmington, North Carolina

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JUL 30 2007
Medical Facilities Planning Section

Submitted by:
Mark Ragozzino MD
Orthopedic and Neurologic Imaging Specialist
Delaney Radiologists
1025 Medical Center Drive
Wilmington, North Carolina, 28401

The 2008 State Medical Facilities Plan proposes a demonstration project consisting of four 4 multi-position, fixed site MRI scanners placed throughout North Carolina. This proposed demonstration project is in response to a petition filed by one for-profit corporation, Axiom Imaging. Axiom imaging is a Las Vegas, Nevada corporation.

The 2007 State Medical Facilities Plan rejected the multi-position MRI demonstration project. We are perplexed to see this demonstration project appear again in the proposed 2008 State Medical Facilities Plan.

This demonstration project is an end run around the well-established need determination process under the guise of medical research. Additionally, the demonstration project flies into the face of the proposed 2008 State Medical Facilities Plan. The plan states that there is no need for additional, fixed-site, open or closed MRI machines in North Carolina.

The multi-position MRI machines called for by this demonstration project are sold only by Fonar Corporation of Melville, New York. The major MRI manufacturers such as General Electric and Siemens have rejected this multi-position design.

Although Fonar MRI equipment has been available to all MRI providers in North Carolina for years, no Fonar MRI machine is installed in North Carolina. The market place, reflecting the needs of North Carolinians, has rejected multi-position, Fonar MRI machines due to poor image quality, cost and other impracticalities.

North Carolina MRI facilities include not-for profit research institutions, non-profit community hospitals, for- profit national corporations and for-profit community medical groups. These varied entities cover a broad spectrum of imaging needs. All have rejected the Fonar multi-positional MRI. .

The purported necessity for the demonstration project is for imaging the spine under load. This argument is specious as a validated spinal loading device is currently available for existing MRI machines. This accessory placed on an existing, standard, open or closed MRI machine can provide higher quality diagnostic information at less cost.

This demonstration project will not provide useful efficacy data. However, it will increase state medical expenditures. Most importantly, it has potential to harm health care consumers. The only beneficiary of this demonstration project is Axiom Imaging, a for-profit corporation based in Las Vegas.

If a useful demonstration project is truly desired, a single multi-position MRI machine should be placed within and under complete control of an academic research center such as Duke or UNC-Chapel, in immediate vicinity of several other competing MRI machines. The demonstration project should specify the testing of well-defined, medically relevant hypotheses and study results should be published in respected, peer-reviewed journals.

The demonstration project proposed by Axiom Imaging for the 2008 State Medical Facilities Plan is disingenuous and simply a ruse to circumvent the well-established need determination process of North Carolina.

MedQuest Associates, Inc.'s
SHCC Public Hearing Comments
Regarding the Adjusted Need Determination
For 4 Demonstration Projects for Multi-Position MRI Scanners
August 1, 2007

MedQuest Associates, Inc. ("MedQuest") is one of the country's leading independent outpatient imaging providers. It operates more than 90 outpatient imaging centers in 13 states including 14 facilities in North Carolina. For more than a decade, MedQuest has actively been involved in the evaluation and selection of MRI scanners for its facilities.

The multi-position MRI ("upright") scanner does not represent cutting edge technology as some would have the State of North Carolina believe. This technology has been available in the commercial marketplace for several years; thus, providers in North Carolina have had ample opportunity to replace existing systems and/or file Certificate of Need applications for "upright" scanners. Further, the "upright" scanner is a 0.6 Tesla system, which provides it no specific image quality advantages over 0.7 Tesla open systems or 1.5 Tesla and 3.0 Tesla closed bore systems. None of the medical teaching facilities in North Carolina have filed applications or petitions for "upright" scanners, indicating that the unique aspects of the unit are of limited clinical value and do not warrant a special clinical "demonstration". Finally, the multi-position MRI scanner proposed does not require a unique CPT code, which means it has not received any special designation by the CPT Editorial Panel.

For the above reasons, MedQuest does not believe that the State Health Coordinating Council should even approve one demonstration project for a multi-position MRI scanner, much less four scanners of this type. MedQuest believes that the primary intent of this request is to acquire additional MRI scanner capacity outside of the normal MRI methodology. Any current provider of MRI services has the ability to upgrade or replace an existing MRI scanner. To date, none of the MRI providers in North Carolina has chosen to acquire this type of MRI scanner through that process. Current providers and applicants for MRI services also have the opportunity through the CON process to

propose a multi-position scanner in a normal CON review. There is no need for a demonstration.

If the SHCC decides to proceed with a demonstration project, then MedQuest requests that the SHCC consider the following:

1. **Limit the demonstration project to one multi-position scanner for the State.**

This request is consistent with prior demonstration projects such as the dedicated breast MRI scanner and pediatric MRI scanner.

2. **Limit the use of the multi-position scanner to spine-only studies and in an upright position.**

Since the petitioner has argued that the purpose of the multi-position scanner is to allow patients in need of spine studies to stand upright during the exam, then the approved applicant should be limited to these studies. This is consistent with the theory of allowing demonstration projects and with the requirements previously made of the dedicated breast MRI scanner and pediatric MRI scanner.

3. **Do not allow the provider to replace the multi-position scanner with a conventional fixed or mobile MRI scanner.**

In order to prevent demonstration projects from becoming a loophole method for obtaining a fixed MRI scanner, the SHCC should mandate that a provider approved for this demonstration project cannot replace the multi-position scanner with a conventional fixed or mobile MRI scanner. If the scanner becomes obsolete after five or ten years and the provider cannot replace the equipment with another multi-position scanner, then it should be required to relinquish its certificate of need for the project.

Thank you for the opportunity to comment on this issue.

Bruce Elder

Bruce Elder
Vice President, Development
MedQuest Associates, Inc.

Wake Forest University Baptist

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AUG 02 2007

Medical Facilities
Planning Section

August, 2 2007

Michael L. Freeman
Vice President
Strategic Planning

Telephone: (336) 716-5097
Fax: (336) 716-2879
freeman@ufubmc.edu

Mr. Robert J. Fitzgerald, Director
Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Mr. Fitzgerald:

I am writing to reiterate the concern Carolina's Healthcare System has expressed with respect to the proposed demonstration project for four fixed multi-position MRI scanners contained on page 139 of the Proposed 2008 State Medical Facilities Plan (SMFP). I am also recommending this section of the proposed SMFP be changed to include only two multi-position scanners (one for each side of the state). Including two scanners in this demonstration project will allow the State to evaluate the benefits, utilization and payer mix trends of the project before additional scanners of this type are placed in the SMFP. This approach is more consistent with how the State has handled the past three MRI demonstration projects, including breast, extremity and pediatric, whereby only one scanner was available under the initial demonstration.

The rationale for this recommendation as summarized by Carolina's Healthcare System includes the following points:

- Our recommendation is similar to the original direction provided by the Technology and Equipment Committee to include one scanner to represent each of the three eastern and three western HSAs, which would equate to only two scanners statewide.

- On May 30, the SHCC voted to increase the Technology and Equipment Committee recommendation from two scanners to four. During this SHCC meeting, I also believe the members of the SHCC did not have full knowledge of the facts surrounding this technology as follows:

    - Based on our research, the manufacturer of the demonstration scanner is Fonar. To date, Fonar has sold only 120 scanners worldwide over the past eight years. With the proposed demonstration project as is, North

Carolina is proposing to add three percent to the worldwide market inventory for this particular scanner.

- The proposed scanner is a 0.6T MRI system. Image quality for this particular scanner is noticeably inferior to 1.5T and 3.0T systems. 0.6T scanners and similar lower field strength MRI systems have been and/or are being phased out by several owners of this equipment in the State.

- It is also noted that the multi-position scanner proposed in the demonstration project has been available for sale in North Carolina for the past six years. During this period of time, no physician practice, imaging center or hospital has purchased the multi-position scanner proposed in this demonstration project.

I appreciate the opportunity to offer my recommendation and comments to you as your staff and the SHCC work to finalize the 2008 State Medical Facilities Plan over the next several months. If you should have any questions regarding the above information and comments, please feel free to call me at (336) 716-5097.

Sincerely,

Michael L. Freeman

Michael L. Freeman
Vice President, Strategic Planning

Greensboro PH
7-20-07
MRI
TOM

Comments on the petition for an upright MRI
Proposed NC 2008 SMFP
David C. Clark MD
Greensboro Radiology
July 20,2007

The proposed demonstration project for upright MRI is opposed for the following reasons:

1. There is a lack of scientific evidence showing improved patient outcomes or more accurate diagnosis using an upright MRI as opposed to the current standard MRI systems. The Axiom Imaging Petition claims a "Failed Back Syndrome" of 5% to 40% following spine surgery, and implies that their upright MRI would improve this rate, but provide no evidence to support this claim. The Axiom petition claims that North Carolina residents are being harmed by lack of access to this technology, but upright MRI equipment has been available for 8 years and no units have been purchased in North Carolina which speaks to lack of demand for this technology in the marketplace. Upright MRI should be regulated as any other MRI system is in North Carolina. There are hundreds of orthopedic surgeons in North Carolina, none provide written support for this technology in the petition.
2. The criteria for approving demonstration projects for MRI has not been defined. This opens the door for vendors and providers to lobby to obtain profitable technology outside the current CON process. Without written criteria, the DFS runs the risk of creating a precedent for requests for multiple future demonstration MRI projects based on vendor and medical provider financial gain, rather than improvements in public health. Without clarity of the rules, it is likely that future demonstration project requests will appear with minor variations from current technology, as a means to get new magnets in the marketplace. I suggest that this and future MRI demonstration project requests be suspended until written criteria are developed that specify:
   a. Criteria for making a petition for a demonstration project for MRI
   b. Criteria for approval for the demonstration projects
   c. Data to be collected and how this data will be used to make future decisions
3. Petitions for MRI demonstration projects based solely on technology variations should be denied. Technology is constantly changing, and today's latest and greatest technology may be obsolete by the time the demonstration project is operational.

4. The petition for upright MRI should be disapproved because there is no evidence that it will benefit the health of North Carolinians. The primary beneficiary of this technology will be the vendor selling the product as there is only one vendor producing this equipment, and the provider of the service. The vendor should compete in the marketplace for sales, through the replacement process of existing MRI units.

5. Upright MRI is a one trick pony. Its only proposed benefit would be to perform MRI under upright axial loading conditions. However, it is a 0.6 Tesla unit which inherently has longer scan times and inferior image quality than a standard 1.5 Tesla unit. This combined with upright scanning is likely to have a higher incidence of patient motion. Therefore, if the upright MRI demonstration project is approved, I recommend that the only procedure performed on the scanner is upright imaging in order to gather data to make future determinations regarding the validity of the technology. Limiting imaging on the demonstration MRI to upright imaging is appropriate and consistent with prior restrictions placed on breast and pediatric CON demonstration projects. It would also prevent substandard imaging on equipment that could be better performed on existing high field technology.
6. There is not a unique CPT code for upright MRI. This was submitted to the CPT Editorial Panel but denied. Without a unique CPT code, this procedure is considered experimental and may not be reimbursed by some carriers.
7. Insurance companies and Medicare are attempting to reduce imaging utilization; the upright MRI would have the opposite effect by bringing in a new unproven technology which would promote experimentation. Lacking any defined criteria for performing upright spinal MRI makes selection of patients for this technology arbitrary.
8. Should the demonstration project be approved, appropriate data should be collected from the approved site so that future determinations can be made regarding the technology. If approved, one upright MRI scanner should be adequate to gather data on the validity of this technology, not the four scanners currently requested. At minimum, the following should be included:

    - The number of MRI examinations performed on the unit
    - The total number of upright MRI studies performed on the system
    - CPT code data for all examinations
    - Patient payer mix including Medicare, Medicaid, insured and uninsured
    - Referring physician examinations
    - County of residence of all patients having the examination
    - The demonstration MR facility must operate a minimum of 66 hours per week. The facility revenue and operating expenses should be included in the reporting documents.
    - Full disclosure of the MR system and site ownership including the names of all physician investors and their relatives. Disclosure of any consultant payments, lease arrangements, and assigned billing arrangements should be disclosed.
    - Documentation of the number of cases where outcomes and or patient management decisions were impacted by the upright MRI

WAKE RADIOLOGY

CONSULTANTS, P.A.

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Planning Section

DIAGNOSTIC RADIOLOGY
[illegible]
..., M.D.

RADIATION ONCOLOGY
Andrew S. Kennedy, M.D.
Scott L. Sailer, M.D.
William A. Dezarn, Ph.D., DABR

ADMINISTRATOR
W. H. Johnson

BUSINESS MANAGER
B. V. Hill

July 24, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

RE: Comments Submitted for Public Hearing Proposed 2008 State Medical Facilities Plan: Upright MRI Demonstration Projects

Dear Mr. Elkins,

The following comments are in reference to the proposed 4 Upright Fonar MR demonstration projects in the 2008 Plan. Upright MRI is exclusively manufactured by a sole source vendor, Fonar, which has sold approximately 120 systems worldwide in the past eight years. Nothing in the current CON process discriminates against Fonar's technology, any future applicant or replacement system can obtain permission to install or replace an existing MR with an Upright Fonar system under the current methodology. The inclusion of this technology as a demonstration site is undoubtably manufacturer driven. Frankly, 4 demonstration sites equal four sales for Fonar. Given that there is no current restriction on Fonar selling these instruments to North Carolina providers, why then is there a need for 4 demonstration projects?

If the State has determined the necessity for an Upright MR demonstration project, one site should accomplish the task not unlike the breast MR, pediatric MR, and extremity MR demonstration projects now in process.

Indeed, if the State believes there is a need for more than one Upright MR demonstration project, then the additional allocations for these projects should be granted to one or more of our four academic teaching centers. For if the demonstration projects are to prove or disprove the technology, who better to run the additional projects then Duke, Wake Forest, UNC, or ECU?

3949 Browning Place • Raleigh NC 27609
www.wakeradiology.com

The forgoing discussion highlights the need for the Division of Facility Services to establish criteria for demonstration project petitions in an effort to discourage manufacturer driven sales agendas from overwhelming the State's process.

At the end of the day, Upright MRI is just a technology variant currently available through the existing process. If the State approves the demonstration project, one site should provide the necessary results. Any other provider can obtain this technology through the normal application or replacement process now in place.

Sincerely,

Robert E. Schaaf, MD
President and Managing Partner
Wake Radiology

Asheville PH
July 13, 2007
Jim Montgomery
Ninth posting MRI

Comments for Public Hearing
Proposed 2008 State Medical Facilities Plan
Asheville
RE: Multiposition MRI-Demonstration Project(s)
13July2007

1. The original suggestion for the demonstration project was for one upright MRI scanner for the HSAs I-III and one for HSAs IV-VI. This was changed to a total of FOUR scanners. The proposed 2008 SMFP on Table 9Q(1) shows that there are only 11 MRI scanners in the total State's need determination. Thus the Plan is recommending adding 36% more scanners to the Plan that the original need determination. There is no reason to add this many multiposition scanners, especially given that they are a demonstration project.

2. Multidirectional scanners are "Low Field" technology. All the medical centers in North Carolina are installing 1.5 or 3.0 T technology, not 0.7 T. This project seems to be going the wrong direction.

3. Some argue that patients are being disadvantaged by not having this technology available. This is ridiculous, these scanners have been available for years. There are none of these scanners in use in NC because doctors and hospitals have chosen not to buy them. Asheville Radiology owns or operates six scanners. We consider this technology to be inferior and out of date

4. The literature regarding multipositional MRI is commonly biased by a manufacturer's sponsored outcome, not based on evidence based medicine.

5. If any of these scanners ultimately appear in the Plan, they should be *limited to scanning only the spine* and all numbers carefully reported.

6. Most importantly, the *scans must all be done in the upright position*, as this is the reason the scanners were added to the Plan.

7. If hospitals or physician groups feel they need a multipositional MRI, they have the option of replacing existing equipment with a multipositional MRI.

8. There is no credible clinical outcome data to support a multipositional MRI scanner over a conventional scanner.

9. The multipositional scanners are very expensive. Absent positive clinical data and considering the low field technology, there is no justification to add one to the Plan, much less four.

10. The CPT Editorial Panel refused to provide a unique code for upright MRI because of the lack of meaningful outcomes data showing its superiority over conventional MRI.

11. Image quality on a 0.7T MRI scanner is inferior to 1.5T or 3.0T, no matter what direction the magnet is oriented.

12. 0.7T magnets are slower, result in more patient motion, and are more likely to miss small abnormalities because of technical limitations.

13. Abdominal and vascular MRI are of very low quality at 0.7T. Thus, utilization of these scanners will be limited.

14. Fonar makes the multipositional scanner. It has no installations in North Carolina and only a few dozen in the world. No major vendor of MRI equipment (GE, Siemens, Philips) is making a multipositional scanner.

15. If this demonstration project is allowed and a hospital – or more likely, a physician practice – takes on one of these scanners, it should not be replaced for a minimum of five years.

16. CPT code data should be generated and reported to the Agency for all examinations.

17. The patient payer mix must be reported as part of the demonstration project and those results should mirror the region's demographics.

18. To insure compliance with State and Federal Law, disclosure of the magnet's owners (and their relatives), physician investors, consultant payments, and any lease arrangements should be reported to the Agency.

19. Previous demonstration projects have limited utilization of the project MRI scanner to Breast and Pediatric imaging. This project, if implemented, should be limited to the spine and as mentioned above, should be performed upright.

20. Detailed billing data should be reported to allocate technical and professional charges to the provider that actually performed the service.

21. If NC were to allow 4 multipositional scanners in the 2008 Plan, we would likely be placing more of these scanners in our state than any other state in the country. These are uncommon scanners in the marketplace simply because their quality, speed, resolution, and cost [redacted] cannot compete with modern scanners.

22. If a demonstration project is approved, allocation of ONE scanner for demonstration is sufficient. This will allow data to be collected and analyzed to determine if any additional scanners are justified.

Summary: Multipositional MRI is a perfect solution to a problem that does not exist. The numerous experts in our prestigious medical centers and private practices in North Carolina have chosen *not* to buy upright scanners, even though they have been on the market for years. They are too expensive, too slow, and image quality is inferior to scanners currently being sold by most vendors. Evidence based medicine fails to show a driver for this technology.

Rec'd @ July 24 2007 Greenville Public Hearing.

ERI Eastern Radiologists, Inc.

Providing Subspecialty Imaging and Interventional Services to 29 Counties through University Health Systems of Eastern Carolina

Comments for Public Hearing regarding Multi-Position MRI Demonstration Projects
Proposed 2008 State Medical Facilities Plan
July 24, 2007

Eastern Radiologists, Inc. has significant concerns regarding the proposed demonstration project for upright MR for the reasons outlined below:

1. The primary issue is that there is insufficient scientific evidence related to clinical outcomes showing that a multi-positional MR scanner improves patient outcomes or provides more accurate diagnosis than current standard MR systems. The ideal demonstration project would require that the upright MR be placed in an academic medical center or other site where diagnosis and patient outcomes can be compared to standard 1.5 T high field systems in a well designed research protocol which would in turn be published in a peer reviewed medical journal.

2. Demonstration CON's in the State of North Carolina have generally been limited to one device. Authorizing four simultaneous CON's is much more than is needed for a demonstration project and essentially creates a new regulatory class for MR. One unit, or at most two units would be preferable for a demonstration project. The Fonar unit is the only upright MR available. There are 120 Fonar systems worldwide after being on the market for eight years. The proposed four unit CON demonstration project would add 3% to the worldwide installed base and would probably account for more than 20% of Fonar's yearly sales.

3. The only existing upright MR is a 0.6 Tesla system manufactured by Fonar. The majority of hospitals and imaging centers in North Carolina and across the country are moving towards high field systems at 1.5 or 3 tesla due to faster imaging times, higher single to noise, and overall improved diagnostic accuracy. Higher field strength results in improved imaging across a wide range of clinical applications. The Fonar MR system does poor vascular and body imaging due to a combination of its configuration and low field strength. Theses shortcomings likely explain why although new applicants and existing holders of MR CON's have the option to convert existing systems to upright MR, no conversions have yet occurred. The failure of this product to make significant inroads in the MR marketplace, coupled with the lack of concurrent development by other MR vendors, highlights the significant limitations of this design.

4. A unique CPT code does not currently exist for upright MR. The editorial panel recently denied this request. Without a unique CPT code, upright MR may be considered experimental and may not be reimbursed by some carriers.

5. Insurance companies and Medicare are currently trying to reduce imaging utilization. This upright MR demonstration project would have the opposite effect by bringing four

#9 Doctors Park - Greenville, NC 27834 - (252) 752-5000 - (800) 682-6956 - Fax (252) 752-0166 - http://www.easternrad.com

additional units with unproven technology into the state of North Carolina.

6. We are concerned about the lack of criteria for approving demonstration projects in MR. The primary beneficiary of this technology will likely be a single vendor making an unusual product which has not yet been accepted by the medical community. This demonstration project may set a precedent for vendors and providers to lobby for other technologies outside of the CON process as well.

If the state of North Carolina does proceed with this program, we recommend the following requirements:

1. The project should require that the upright MR be placed at a site where diagnosis and patient outcomes can be scientifically compared to standard 1.5 T high field systems in a well designed research protocol which would in turn be published in a peer reviewed medical journal.

2. Full disclosure of the MR system and ownership including all names of physician investors and the relatives, as well as consultant payments, lease arrangements, and billing arrangements including itemized billing with specific identification of technical and professional charges and who provided those services as submitted for payment.

3. Report the referring doctor and patient origin data for each exam should be reported.

4. An annual report should be made to the CON in a medical facilities planning session to report the number of MR exams actually performed in the upright position, the total number of exams performed by the system, the CPT code for all exams, and the patient payer mix of including uninsured and underinsured.

5. Spinal imaging is the major focus of this project and the only application for which this system has been suggested to have an advantage. It is recommended that imaging be limited on the demonstration project CON to only spinal imaging. Similar restrictions have been put in place for breast and pediatric CON demonstration projects in the past and would maximize the data value of this demonstration project.

Sincerely,

Michael McLaughlin, MD, MBA
President
Eastern Radiologists, Inc

Technology and Equipment Committee Meeting

August 29, 2007

MRI MATERIAL

Material Related to

Other MRI Comments

Carolinas Medical Center
Lincoln

Pete Acker
President & Chief Executive Officer

August 1, 2007

Dan A. Myers, M.D.
Chairman, North Carolina State Health Coordinating Council
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

RE: Comments on the Proposed 2008 SMFP Need Determination for One Fixed MRI Scanner in Lincoln County

Dear Dr. Myers:

On behalf of Carolinas Medical Center-Lincoln (CMC-Lincoln) and the residents of Lincoln County, I want to express my support for the need determination in the *Proposed 2008 SMFP* for one fixed MRI scanner in Lincoln County. As one of only two hospitals in the state with more than 100 beds but without a fixed MRI scanner, we certainly believe there is a need for a fixed MRI scanner to provide adequate diagnostic imaging services to our county's residents, including our inpatients, emergency patients and outpatients. CMC-Lincoln is the sole community hospital provider in the county, providing care to more than 70,000 residents without regard to the patient's age, race, national or ethnic origin, disability, gender, income or ability to pay.

CMC-Lincoln appreciates the Council's willingness to recognize the continuing growth in the number of MRI procedures performed on the mobile MRI unit and the resulting need for a full-time, fixed MRI scanner in the county. We believe that the allocated scanner will expand access to this vital imaging modality for our patients.

If we can be of any assistance to the SHCC as the development of the final *2008 SMFP* continues, please do not hesitate to contact us.

Respectfully yours,

Pete Acker

Peter W. Acker
President and Chief Executive Officer

Fax 919 715-4413

Strategic Healthcare Consultants

DFS Health Planning
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AUG 03 2007
Medical Facilities Planning Section

August 3, 2007

Mr. Tom Elkins
Medical Facility Planning Section
NC Division of Health Service Regulation
701 Barbour Drive
P.O. Box 29530
Raleigh, NC 27626-0530

RE: Comment Regarding Proposed 2008 State Medical Facilities Plan, Chapter 9, MRI Section, Table 9O, Page 133

Dear Mr. Elkin,

I am writing on behalf of Park Ridge Hospital in Henderson County regarding the Proposed 2008 State Medical Facilities Plan. As we discussed, the MRI inventory on page 133 of the Proposed Plan lists Park Ridge Hospital as having both a mobile MRI scanner and a fixed MRI scanner.

Please note that Park Ridge Hospital obtained CON approval to replace its previous mobile MRI scanner with a fixed unit. Park Ridge Hospital has removed the mobile MRI unit from North Carolina and has implemented the fixed MRI scanner in accordance with the CON conditions.

Table 9O shows the "fixed equivalent magnet subtotal" for Henderson County that includes the values of both of the mobile and fixed units which creates the possible impression that both units were simultaneously in use. However this is not the case. The Park Ridge Hospital fixed and mobile MRI units were not in simultaneous use.

Please accept this correspondence as a clarification of the data reflected in the Proposed 2008 Plan. If you have any questions please call me at 336 349-6250.

Sincerely

David French
Consultant to Park Ridge Hospital

Phone: 336-349-6250
Fax: 336-349-6260

Mailing Address
Post Office Box 2154
Reidsville, NC 27323-2154